Public money, public goods?

The Bayh Dole Act and its "manufactured substantially" provision

Sunniva Jane Stokkan Smith

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Department of Comparative Politics
University of Bergen

Abstract

The Bayh-Dole Act of 1980 allows private institutions and small businesses to patent the results of federally funded research. One of the goals of the Act is to promote the commercialization and public availability of inventions made in the United States by United States industry and labor. This is to be realized through section 204 of the Act, which requires recipients of federal research funding to manufacture any products of that research in the US. Despite the importance of section 204, there is currently no research, peer-reviewed or otherwise, that evaluates its effects on domestic manufacturing. This thesis attempts to close this research gap by investigating and evaluating the Act's 204 provision's effect on the domestic manufacture of pharmaceuticals created with federal funding from the National Institutes of Health.

This thesis attempts to explain the Act's mechanisms of causality. It does so by presenting and discussing the causal mechanisms that proponents of the Act put forward in hearings held prior to enactment. Through original research, it investigates the impact of section 204 on the domestic manufacture of pharmaceuticals created with federal funding. By employing the method of process tracing, I detective-like searched for empirical data for the only theorized causal mechanism of the 204 provision found in hearings prior to 1980. This led to the creation of an original dataset on the manufacture of NIH-funded pharmaceuticals created between 1982 and 2007. The method of process tracing revealed several issues in the provision, but most importantly the lack of available, transparent data that allows for the true measurement of the 204 provision.

The dataset results show that only ten out of ninety drugs created between 1982 and 2007 are subject inventions and thus subjected to the 204 provision. Process-tracing results show that only four were fully domestically manufactured in the U.S. Five were deemed inconclusive due to data. The research results tell us that there is a possible causal mechanism between the 204 provision and the domestic manufacture of federally funded research, with the policy effect being inconclusive due to data. Further, by comparing the different interpretations and implementations of the 204 provision between federal agencies show that 204 implementation is largely a choice by the federal agency. The investigation and subsequent evaluation of the 204 provision allow for a broader discussion of whether the Bayh-Dole Act still serves its intended purpose.

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Writing about the Bayh-Dole Act has been a challenging process, especially as a long-distance student. I felt strongly that this topic deserved research due to its importance to current American political issues; they hit close to home. I hope this thesis can be some contribution to this issue.

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Table of Contents

List of Tables and Figures:

Abbreviations

Act – The Bayh-Dole Act

204 provision – the 204 “substantially manufactured” provision

FFR – Federally funded research

PPC – Patent policy change

CM – Causal mechanism

PVM – Public Value Mapping

GI - Government Interest

1. Introduction

1.1. What is the Bayh-Dole Act, and why is it relevant today?

Who benefits from publicly funded research in the US? Under the Bayh-Dole Act of 1980, research institutions and their private sector partners are the main financial beneficiaries. The Act automatically grants exclusive rights to institutions and non-profits to license, patent, and profit from the results of federally funded research (FFR) (U.S Congress, House, 1976). Further, a Presidential Memo issued in 1983 allowed large, for-profit corporations to patent FFR. This backtracked a significant aspect of the Act, which was to enhance small business participation in federally funded research and design.

There is a lot of money at stake. The U.S. government spends over $160 billion annually on research and development (R&D) (Kota and Mahoney 2022). The National Institutes of Health, the U.S. federal agency in charge of health research, invested $31 billion R&D in 2022 alone (NIH IMPACT 2022).

Before the Bayh-Dole Act of 1980, the federal government owned the rights to the results of FFR (Mowery et al. 2001, 102). However, federal agencies could and did grant exemptions to this rule, allowing institutions non-exclusive rights to the results of research done with federal funds (Hemel and Ouellette 2017, 286). Today the Bayh-Dole Act allows institutions that receive federal funds to "patent and exclusively license federally funded inventions" (Thursby og Thursby 2003). Thus, the Act's passage enabled a large-scale transfer of rights regarding FFR from the public to the private sector.

During Congressional debates over the passage of the Act, the most common justification for the Act was a set of assumptions about the state's role in technology development and commercialization. Advocates for the Act argued that governments are not good at innovating and commercializing technology, while the private sector is (Hemel and Ouellette 2017, 6-7). Granting exclusive rights to research institutions would introduce a profit motive and drive institutions to partner with industry to commercialize their discoveries. This would, in turn, bring the benefits of new inventions to a larger number of people (Hemel and Ouellette 2017, 8)

To offset this transfer of rights from the public to the private sector, the Act contains provisions to ensure public benefits from government funded research. These include a requirement that products arising from publicly funded research be "substantially manufactured" in the US; and a public good provision that allows the government to "march in" and grant non-exclusive licenses to other applicants to drive practical application of the invention or meet the health and safety needs of consumers (Bayh-Dole Act, Public L. 96-517, 1980).

However, most federal agencies have interpreted the Act's public benefit provisions so as to invalidate them. The "substantially manufactured" provision allows the federal agency that funded the research to grant waivers to the research institution (Bayh-Dole Act, Public L. 96-517, 1980). The conditions for waiver are easy to meet, and agencies routinely grant waivers (Struver 2016). In addition, no federal agency has exercised its rights under the "march in" provision as of 2023.

1.1.1. The Bayh Dole Act today

44 years after its passage, the Act is at the core of some of today's most important public policy questions. As mentioned, the Act promotes the privatization of profits from FFR. The question of who should benefit from FFR became newly relevant during the COVID 19 pandemic, as pharmaceutical companies earned immense profits from COVID 19 vaccines developed with FFR (Sekar 2021) (Kollewe 2022). Relatedly, the government's refusal to use the Act's "march-in" provisions has been coupled with the issue of exorbitant prescription drug prices. The NIH recently refused to use "march in" rights to expand production and potentially bring down prices of the cancer drug Xtandi, developed with FFR (Bettelheim 2023). The cost of Xtandi is currently 160 -180 000 USD per patient per year (Reuters 2023).

The Act's "substantially manufactured" provision is also key to broader debates about industrial policy and supply chain security. In theory, section 204 of the Act should have helped to strengthen domestic production by requiring the products of FFR to be made in the US. The opposite seems to be true. The erosion of the U.S. industrial base over the last thirty years is well established (Kota and Mahoney 2022). The consequences include weaker and longer domestic supply chains and rising costs of imported goods (Kota and Mahoney 2022).

In response to these developments, the Department of Energy recently issued new policies requiring domestic manufacturing for some items developed with FFR, citing national security and job creation (Kota and Mahoney 2022) (Department Of Energy 2021).

1.2. The research question and its contribution to the field of study

This thesis uses a deep dive into one of the Act's public benefit provisions, the "substantially manufactured" provision, to explore broader questions about whether the Act has functioned as intended over the four decades since it became law. It focuses on the NIH, which over the years has been responsible for a significant share of the federal government's total R&D funding, and on the pharmaceutical sector, which has been a substantial beneficiary of the Act (NIH IMPACT 2022). Due to data availability, the thesis investigates only inventions created between 1980, when the Act was passed, and 2007. Specifically, the thesis seeks to answer the research question:

> "*Has the Bayh-Dole Act of 1980 and its 204 "substantially manufactured" provision contributed to the domestic manufacture of federally funded inventions at the NIH?*"

To answer the thesis question, I use the method of process tracing. I do this to identify and trace potential theorized causal mechanisms of the effect of the 204 provision and the Act itself. I further process trace and collect empirical data to test the theorized causal mechanism of the 204 provision, which I derived from historical records of hearings held on the Act.

This causal mechanism explains how the Act 204 provision will have an effect on domestic manufacture of FFR. I then discuss the results from my data identification, collection, organization and the creation of an original dataset of said data. I further identify and discuss the meaning of these results, and how it relates to the bigger picture of Act evaluation.

The thesis makes three contributions to research in this field. First, it explains the Act's mechanisms of causality. Second, it investigates the impact of section 204 of the Act on domestic manufacturing, using an original dataset on the manufacture of NIH-funded pharmaceuticals. Related to this, it identifies the challenges of collecting data on the outcomes of the Act. Third, it analyzes whether the Act has had consequences for domestic manufacturing and why or how the causal mechanisms would potentially explain these consequences.

More broadly, this thesis explores unknown territory and attempts to fill several research gaps. There are currently no peer-reviewed articles or NGO reports researching the causality or effect of the 204 provision. The thesis also attempts to "unpack the black box" of how section 204 works and what data supports that. Finally, it identifies needs for further research on the Act.

1.3. Roadmap and presentation of chapters

This thesis has nine chapters: Chapter one is this introduction, which explains why the Act continues to be relevant for major questions of public and industrial policy. Chapter two explains what the legislation is and how it works. Chapter three presents and discusses the political historical context of the Act, and the debate prior to its enactment. This political historical context is crucial to understanding both why Congress passed the Act and the theorized causal mechanisms used to justify its passage. Chapter four presents and discusses studies that directly relate to the research question of this thesis. As there are currently no peer reviewed studies on the causality and effect of the Act's 204 provision, I include the two studies that are most relevant even if not directly on point.

Chapter five presents the theoretical framework and context for the ideas that led to the passage of the Act. This is to create a nuanced overview of the political context for the Act and the theories that underpin that context. Through the examination of historical records of hearings on the Act prior to 1980, I identify the general causal arguments and subsequent mechanisms for how the Act is to create innovation and contribute economic goods. I also identify and present the causal arguments used for why the Act will not have this intended effect. Further, I identify the only found causal mechanism in the historical records of how the Act 204 provision causes domestic manufacturing.

Chapter six presents the methodological framework of this thesis, which is a single-case study and a program effects evaluation, using the method of process tracing (PT). I further present and complete the theorized causal mechanism found in chapter five. Chapter seven discusses the results of the PT, the detective-like search for empirical data to the CM, the findings, the results of the created dataset, the interpretation of said results and how all the pieces fit together. Chapter eight is the analysis. Chapter nine is the conclusion and lays out a future research agenda on the topic.

2. What is the Bayh-Dole Act and how does it work?

2.1. Introduction

The Act's goal is "to increase the distribution of innovative research into the commercial sphere with the help from the private sector" (Perkins and Tierney 2014, 144). Prior to the passage of the Act, the federal government owned the rights to the results of FFR (David C. Mowery et al. 2001, 102). Federal agencies could and did grant exemptions to this rule, allowing institutions non-exclusive rights to the results of research done with federal funds (Hemel and Oullette 2017, 5). Today the Act allows institutions and businesses that receive federal funds to "patent and exclusively license federally funded inventions" (Thursby and Thursby 2003).

Congress passed the Act at a moment when there was deep concern about US leadership in research and innovation. In the 1970s the U.S. had moved from postwar economic leadership to struggling to compete with Japanese and European research, innovation and industry (Stevens 2004, 93) (Perkins and Tierney 2014, 144). Japanese companies dominated technological companies and the automobile industry. The effect of the 1960s and 1970s oil shocks "on an economy dependent on cheap domestic energy" cemented the need for economic rejuvenation (Stevens 2004, 93). Part of the discussion turned to how "best to manage more than $75 billion a year invested in government sponsored R&D" (Stevens 2004, 93).

2.2. The Bayh-Dole Act – how does it work?

2.2.1. Scope of the Act

The Act applies to "all research performed under a federal funding agreement, whether funded in whole or in part by the government" (Henderson and Smith 2002, 3). The Act requires a written agreement between the grantee or contractor and the federal agency , containing the terms of federal funding. The funding terms include two key sets of provisions: The first governs the responsibilities and rights of the grantee and the second lists the responsibilities and rights of government agencies and the government (Henderson and Smith 2002, 3).

2.2.2. Section 202 of the Act

In section 202, Disposition of Rights, the Act allows grantees to choose whether to retain the patent rights to federally-funded inventions. Various responsibilities follow if they do. These responsibilities are included in "the government's funding agreement with each contractor" (Henderson and Smith 2002, 4). For example, section 202 requires that those who choose to hold the patent right "agree to file a patent application prior to any statutory bar date" (Henderson and Smith 2002, 4). The grantee loses patent ownership rights to the government if they fail to file in time. Academic institutions and non-profit contractors seeking patent rights are required to "file a patent application in the United States and grant the government a non-exclusive, non-transferable, paid-up right to practice the invention in the U.S. and throughout the world" (Henderson and Smith 2002, 3). The Act also requires that the contractors take necessary steps to commercialize research or inventions resulting from federally-funded research.

Moreover, section 202 requires the contractors to periodically report to the funding agency on the "utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees" (Henderson and Smith 2002, 4). They also have to report on the income or royalties that stem from inventions with the inventor (Henderson and Smith 2002, 3). Under a separate provision, the government has a responsibility to ensure that licensing agreements of government-owned inventions are accepted "in accordance with the objectives of the Act" (Henderson and Smith 2002, 3).

2.2.3. The public good provisions in Bayh-Dole

The Act includes two public good provisions. The first is the "manufactured substantially" provision, section 204, which "requires contractors to favor U.S. industry for the manufacture of inventions, and small business for the granting of exclusive licenses" (Henderson and Smith 2002, 3). On its face, section 204 requires that products arising from publicly funded research be "manufactured substantially" in the U.S (Bayh-Dole Act, Public L. 96-517, 1980).

However, the “manufactured substantially” provision allows the federal agency that funded the research to grant waivers to the research institution or grantee (Bayh-Dole Act, Public L. 96-517, 1980). The conditions for waiver are easy to meet, and agencies routinely grant waivers (Struver 2016).

The second public good provision is the “march-in” right, section 203. It allows the government to “march-in” and “assume ownership rights of intellectual property when specific provisions of the Act have not been fulfilled, particularly, failure to take necessary steps to achieve practical application of the subject invention” (Henderson and Smith 2002, 3). The government has the right to require that the grantee issue a license “to a third party, including a competitor” and, if the grantee refuses, the government can issue the license itself (Bayh-Dole Act, Public L. 96-517, 1980).

There are four situations in which the government can exercise “march-in” rights. The first, 203(a)(1), is when the grantee has not sufficiently commercialized a product and is not believed to be likely to do so within a reasonable time. The second, 203(a)(2), is when it is “necessary to alleviate public health or safety needs,” and the third is when it is “necessary to meet the public use requirements specified by federal regulations” (Bayh-Dole Act, Public L. 96-517, 1980). Lastly, section 203(a)(4) allows the government to exercise its rights if the grantee “has not substantially manufactured the product in the United States” (Bayh-Dole Act, Public L. 96-517, 1980). The Act gives the agencies the option to march-in if they find violations, but they are not required to. As of today, no federal agency has exercised its rights under the “march in” provision.

Further, although section 203(a)(4) of the Act gives the government the right to march-in if they have found a violation in any of the section 203 sub-sections, 37 CFR 401.6(h) allows federal agencies to walk away from march-in even if they find march-in conditions (37 CFR Chapter IV –Department of Commerce). This regulation is in the Code of Federal Regulations, not in the Act. Essentially, the Department of Commerce wrote a rule stating that the Bayh-Dole does not require federal agencies to march in, and federal agencies don’t have to enforce patent rights clauses required by Bayh-Dole.

2.2.4. Other aspects of the Act

The Bayh-Dole Act of 1980 only granted research institutions, non-profit organizations and small businesses the right to patent federally-funded research (Henderson and Smith 2002, 3). President Reagan then expanded the Act's scope to include large businesses, via Memorandum in 1983. Congress later endorsed this, and the change "allowed for the application of a uniform patent policy applicable to all government contractors of federally-supported research" (Henderson and Smith 2002, 3).

3. The political and historical context for the Act

3.1. Introduction

The core issue behind the passage of the Act was "whether the government or the institutions it funded should retain intellectual property rights in inventions" (Sarpatwari, Kesselheim and Cook-Deegan 2022, 881). The growing role of universities as licensors and patent holders was a large factor in the passage and drafting of the Act (Mowery et al. 2004, 85). Due to increased academic licensing and patenting activity the universities themselves had a large role in the passage of the Act. Even so, "Congress had debated the issue of ownership of patents resulting from publicly funded research for decades before the passage of Bayh-Dole" (Mowery et al. 2004, 85). This chapter recounts that debate, and provides the historical context needed to understand the political motives behind the creation and passing of the Act. This allows us to fully understand the potential causal mechanisms discussed in this thesis.

3.2. 1945 – 1960's – the political debate over state versus private ownership

Public vs. private ownership of FFR was already an important ideological issue in the aftermath of WWII. In debates over the "organization of postwar U.S. science and technology policy", federal patent policy was situated in the middle of arguments on each side (Mowery et al. 2004, 85). In 1945 Senator Harley Kilgore argued when proposing a framework for the National Science Foundation "that government- funded inventions should be published and dedicated to the public, not patented or subject to exclusive licenses" (Sarpatwari, Kesselheim and Cook-Deegan 2022, 881). He argued that they should be in the public domain, and "allowing private contractors to retain patents represented a "giveaway"

of the fruits of taxpayer-funded research to large corporations" (Mowery et al. 2004, 86). This would reinforce the "concentration of technological and economic power". At this point in time patents on pharmaceuticals and medical uses were uncommon—only a few countries had this practice as late as the 1970s (Mowery et al. 2004, 86).

On the opposing side, the arguments were "articulated by the director of the wartime Office of Scientific Research and Development, Vannevar Bush" (Mowery et al. 2004, 86). Bush argued that "allowing contractors to retain patent rights would preserve their incentive to participate in federal R&D projects and to develop commercially useful products based on government-funded research" (Mowery et al. 2004, 86). As will be demonstrated throughout this thesis, not much has changed with this line of argumentation.

3.3. Kefauver, Kefauver-Harris Amendment and the historical context of government-pharma relations

The Kefauver-Harris Amendment to the Food, Drug and Cosmetic Act passed in 1962 in response to the thalidomide scandal in the early 1960s (AIHP 2022). Senator Estes Kefauver, a well-known politician from Tennessee during the 1950s, was key to the passage of this legislation. His hearings therefore provide context for the past and present political issue of pharmaceutical price fixing and the ownership of federally funded inventions. Kefauver proposed corrective legislation, which called for "uniform generic names for drugs, and gave the FDA the authority to pass on drug efficacy as well as safety" (AIHP 2022). This is also relevant to the debate regarding domestic manufacture of FFR (AIHP 2022).

Kefauver investigated big businesses such as auto or steel, organized crime and the pharmaceutical industry prior to the Food, Drug and Cosmetic Act's passing in '62 (AIHP 2022). The context of the pharmacy industry during the 50s is significant to this enactment, which had grown exponentially during the 1950s. Before the 1950s drug companies "were not giants of commerce" (AIHP 2022). Companies built close "relations with pharmacy over the decades and had earned the trust of community pharmacists, who made up nearly 90% of practitioners" (AIHP 2022). The post-war period spurred large amounts of investment and subsequent research in drug development and antibiotic research (AIHP 2022). This caused large cash flow to drugstores.

Between 1959 and 1960, Senator Kefauver and his committee went after pharmaceutical drug pricing (AIHP 2022). The senator "was convinced that the pharmaceutical industry was fixing prices on certain drugs, especially antibiotics". The accusations were strongly refuted. Kefauver struggled with the hearings, as the companies opposed his inquiries. The pharma industry saw the Kefauver hearings as a threat to impose price controls on drugs, especially those that were lucrative.

Most importantly, Kefauver's hearings "brought public attention to the subject of generic prescribing and its possible cost savings" (AIHP 2022). Almost all drugs were prescribed by trade name. Millions of dollars were spent on marketing such names, and "anti-substitution laws kept brand name medicines large sellers long after patent rights expired" (AIHP 2022). Kefauver's hearings further found that brand name drugs manufactured by U.S. companies were being sold at a much lower price in Europe and Canada than in the U.S. This was explained away as a consequence of a strong dollar.

3.4. 1960s- to the passage of the Bayh-Dole Act

3.4.1. The Harbridge House report and its importance to the context

The Harbridge House report from 1968 marked an important step towards shifting the "default away from government ownership" of intellectual property rights (Sarpatwari, Kesselheim and Cook-Deegan 2022, 882). Commissioned by the White House, the report was "to examine government patent policy". Specifically, it found that "many patents held by the government had not been commercialized" (Sarpatwari, Kesselheim and Cook-Deegan 2022, 882). This led to the myth of "28,000 unlicensed government patents", commonly used as an example of government inefficiency in commercializing research. In reality, "the vast majority (83%) of the patents in the report arose from the Department of Defense under funding agreements that enabled contractors to seek patent rights if they chose" (Sarpatwari, Kesselheim and Cook-Deegan 2022, 882). In addition, "the government-owned patents were passed over for commercialization by private industry before the government sought patents" causing many patents to be un-commercialized. Thus, there was confusion about the role of the State in both R&D and commercialization many years prior to the Act.

The supporters of government-owned patents also argued that allowing contractors to "retain title to patents resulting from FFR favored large firms at the expense of small business" (Mowery et al. 2004, 86). Further, a policy change would raise the prices of the inventions stemming from taxpayer-funded research. On the opposing side, the argument was that not allowing contractors to retail title to patents would make it less attractive for qualified companies to perform government research, and lessen the incentive to invest in commercial development of said research (Mowery et al. 2004, 86). A uniform patent policy across all federal agencies was also a large issue in these debates (Mowery et al. 2004, 87).

Although it has been argued that government patent ownership interfered substantially with pharmaceutical innovation, there were many successful vaccine and drug programs directed by the government during WWII. The programs entailed "academic medical research, with manufacturing performed by private firms" (Sarpatwari, Kesselheim and Cook-Deegan 2022, 882). At the same time of the Harbridge House report, academic scientists generally avoided patents on medical products. Not only were there few patents to license, but large universities as Columbia, Johns Hopkins and Harvard "had formal policies against medical patents" (Sarpatwari, Kesselheim and Cook-Deegan 2022, 882). A few exceptions existed: there were academic patents on insulin, vitamin D, cortisol and more.

The Harbridge House report also contained an analysis of NIH programs for medication development. The analysis showed that until 1962, "NIH researchers used private pharmaceutical firms to screen tens of thousands of compounds for subsequent government-funded collaborative research, with no written agreements" (Sarpatwari, Kesselheim and Cook-Deegan 2022, 882). Collaboration ceased when the NIH wanted government rights in medications that were successful.

After the release of the Harbridge report in 1968, and reports on the NIHs Medical Chemistry program by the U.S General Accounting Office (GAO) the same year, federal policy towards patents from publicly funded research became even more central in the debate (Mowery et al. 2004, 88). In fact, both reports criticized the Department of Health, Education, and Welfare (HEW) patent policy, and recommended they change it. Specifically, they called for clarification on "which rights reverted to the government and those under which universities could retail title to patents and issue exclusive licenses to firms" (Mowery et al. 2004, 88).

3.4.2. The course of patent policy from 1963 to 1977

The decision by the NIH to hire Norman Latker in 1963 was a factor in the changing course of university patenting. During the 1960s Latker pushed HEW to change its patent policy that would later "be critical to both increasing university patenting directly and ultimately to passing the Bayh-Dole Act" (Berman 2006, 11-12). The first five years working at HEW was spent establishing "an administrative mechanism that would encourage university patenting of NIH-funded research". And in 1968 this became a reality, partly due to the Harbridge and GAO reports (Mowery et al. 2004, 88).. The NIH approved the institutional patent agreement (IPA) framework written by Latker, "which allowed research institutions to elect title to inventions under their government funding agreements" (Sarpatwari, Kesselheim and Cook-Deegan 2022, 882).

In the time between 1969 and 1974 HEW "approved 90 percent of petitions for title" (Mowery et al. 2004, 88). The National Science Foundation also adopted a similar IPA program in 1973, and the Department of Defense (DOD) began in the mid-1960s "to allow universities with approved patent policies to retain title to inventions". Thus, by the start of the 1970s U.S universities were "able to patent the results of FFR via agency-specific IPAs or similar programs". This resulted in U.S universities becoming much more active in patenting.

When Congress adopted this framework, ownership rights were conferred to research institutions, firms and the universities that employed them (Sarpatwari, Kesselheim and Cook-Deegan 2022, 882). Leading up to the passage of Bayh-Dole, debates centered on the "legislator's preference for universities and small business over government, with relatively less attention to the inventors". The program ran up until Joseph Califano was appointed Secretary of HEW in 1976. Califano and his legal advisors were "opposed to giving away government patent rights" (Sarpatwari, Kesselheim and Cook-Deegan 2022, 883).

The IPA programs and policies caused much debate within HEW. Califano had expressed "concern that the university patents and licenses, particularly exclusive licenses, could contribute to higher health-care costs" (Mowery et al. 2004, 89). Renewals of IPAs came to a halt, and a 1977 memo "proposed reversion to government ownership and dedication of patents to the public". Latker managed the IPAs for the department, and drafted a rebuttal, "pointing out the importance of patent rights to induce investment in proving drugs sufficiently safe and effective" (Sarpatwari, Kesselheim and Cook-Deegan 2022, 883). Latker

was later fired by Califano (Stevens 2004, 95). And although the Carter administration was very much opposed to the IPA framework, Latker was later reinstated (Stevens 2004, 95).

3.4.3. The passage of the Bayh-Dole Act

Though Bayh-Dole is often seen as the catalyst for growing university patenting and licensing in the U.S, U.S. universities were active in both areas long before (Mowery et al. 2004, 89). In fact, universities both lobbied for the introduction and passage of the bill. Subsequently, in response to HEW's review of the patent policies, "universities got upset and complained to Congress" (Mowery et al. 2004, 89). The instruction of the bill by Senators Birch Bayh (D-Ind.) and Robert Dole (R-Kans.) happened due to the requests from employees working at universities seeking more liberal policies toward patenting of publicly funded research (Mowery et al. 2004, 89). Other university licensing officials also "aided in drafting portions of what became the Bayh-Dole Act".

Senator Dole held in 1978 a press conference criticizing HEW for "stonewalling" university patenting, and subsequently announced the intention to introduce a bill called the University and Small Business Patent Act. The Act "proposed a uniform federal patent policy that gave universities and small businesses the rights to any patents resulting from government-funded research" (Mowery et al. 2004, 89). Not only did the bill lack provisions included in most IPAs, but it also "imposed no restrictions on the negotiation by universities and other research intuitions of exclusive licensing agreements" (Mowery et al. 2004, 89).

The idea of granting ownership of patents to research performers or contractors was long opposed by many members of Congress. Yet, the Act was passed with little opposition. The focus on securing patent rights for only small businesses and universities "weakened the argument that such patent-ownership policies would favor big business". There was backlash from Califano's blocking of IPAs, which, "combined with fear of being overshadowed by Japan, enabled passage of the Bayh-Dole Act and its framework" (Sarpatwari, Kesselheim and Cook-Deegan 2022, 883). In addition, the lobbying from large universities and their testimony during hearings, as well as being active "in commenting and helping develop the final language" of the bill, contributed to its passage.

3.5. Chapter conclusion

In this chapter I have recounted the historical political context of the Act. To quickly sum, the debate between private vs public ownership of FFR has existed since the 1945s. Today, many of the arguments are the same. The issue of pharmaceutical drug pricing today mirrors issues discussed in the Kefauver hearings. The Harbridge House Report issued in 1968 represents some of the first shifts away from public ownership and further perpetuated the myth of a bureaucratic government incapable of innovation, even though the government had long been financing and delivering successful drug and vaccine programs. The introduction of the IPA programs in 1968 further cemented this shift. Although universities had been patenting and licensing long before the Act, universities and lobby groups were key to the passage of the Act. Mounting pressure to create a larger role for the U.S. in innovation eventually allowed the Act to pass in 1980.

4. Literature review

4.1. Introduction

As mentioned earlier, there is no peer reviewed research that measures the effectiveness of the Bayh-Dole Act 204 "manufacturing substantially" provision. Likewise, there are few articles or NGO projects discussing this provision. Therefore, this chapter discusses other research that evaluates the Act, its effects, its causal mechanisms, and the economic contributions of the Act. Although this research does not address section 204's "manufactured substantially" provision specifically, it helps to illuminate some of the issues raised by the thesis question.

4.2. Short summary of the Bayh-Dole Act

To reiterate, the policy and goal of the Act relevant to the research question is: "to promote the commercialization and public availability of inventions made in the United States by United States industry and labor" (Bayh-Dole Act, Public L. 96-517, 1980).

The Act allows private research organizations, institutions, and (after 1983 via Presidential Memo) large for-profit corporations to patent inventions or research created fully or partially with federal funding (Bayh-Dole Act, Public L. 96-517, 1980). The Act passed with the

argument that there must be an incentive for participation in FFR to increase innovation (96 U.S. Congress, Senate, Committee, S. 414). The incentive is the exclusive license to commercialize FFR. According to proponents of the Act, this would increase the rate of commercialized research, create jobs and more economic goods (96 U.S. Congress, Senate, Committee, S. 414).

Section 204's "manufactured substantially" provision is on its face a public good provision to ensure the domestic manufacture of FFR. In essence, it requires that products arising from publicly funded research be "manufactured substantially" in the U.S (35 U.S. Code § 204 - Preference for United States industry). The "manufactured substantially" provision allows the federal agency that funded the research to grant waivers to the research institution or grantee. The conditions for waiver are easy to meet, and agencies routinely grant waivers (Struver 2016).

4.3. The causal mechanisms for university-industry technology transfer

The book *Ivory Tower and Industrial Innovation: University – Industry Technology Transfer before and after the Bayh-Dole Act* studies the explosive growth in university patenting and licensing activities since the early 1980s. The Congressional Joint Economic Committee and others believe that this activity contributed to the economic boom of the 1990s (Mowery et al. 2004, 179). Others saw this growth as a result of the Bayh-Dole Act of 1980. The book assesses the Act and tests commonly argued causal mechanisms by using quantitative data and detailed case studies. The authors further examine "the diverse channels through which commercialization has occurred over the 20th century and since the passage of the Act" (Mazzoleni 2004)

4.3.1. What does research say?

The authors argue that the role of the Bayh-Dole Act was exaggerated in the discussion of the economic role and contributions of U.S universities and research universities (Mowery et al.. 2004, 178). Although they found that U.S universities have been key to industrial innovation, a large part of their economic contribution relied on other channels than patenting and licensing (Mowery et al.. 2004, 179). University research influences industrial innovation and vice versa throughout several diverse channels, all of which have to be recognized in order to assess the true economic role of universities.

In the book Mowery et al. sought to answer the question "did the Bayh-Dole Act and the growth in university patenting that characterized the 1970-2000 period increase the contributions of university research to the "New Economy" in the United States in the 1990s?" (2004, 183). They found that there was no evidence to suggest that the contributions made during the '80s- '90s were more important than those made in the '30s or '40s. Further, they did not find any evidence to suggest that these contributions were due to the Bayh-Dole Act, as university patenting and licensing was on the rise before the Act's passage. In addition, they did not find evidence that these contributions were dependent on the Act (Mowery et al.. 2004, 183).

The contributions made by universities are created within a higher education system, which contrasts with other industrial systems of innovation. Universities maintain relationships with outside groups for research and expanding new fields and techniques in science that are relevant for their constituents. Thus, Mowery et al found that technology transfer does not depend on universities possessing intellectual property rights (2004, 184).

4.3.1.1. The historical role of University patenting and its channels of contribution prior to the Act

U.S. research universities and organized industrial research have developed a "complex and interactive relationship" (Mowery et al.. 2004, 180). The U.S higher education infrastructure consisted of financial autonomy, public funding at state and local level, federal research support, and substantial scale. This infrastructure created strong incentive for university staff to focus on "research activities with local economic and social benefits" (Mowery et al.. 2004, 180). Federal support for university research increased in the 1940s, and federal agencies had two clear missions with federal funding: national defense and public health. Thus, post-war university research heavily focused on basic research with "a focus on the use of that understanding for solutions to specific problems or missions" (Mowery et al.. 2004 180). Although many universities had adopted a patent policy by the 1950's, many of these policies prohibited patenting of inventions, and patenting was in general less common.

Universities and especially private universities expanded their patenting and licensing activities in the 1970s, but especially in the biomedical fields. A contributing factor to this expansion is the agreements between individual government research funding agencies and universities (also called the IPAs) (Mowery et al.. 2004, 181). Thus, one of several factors to the passage of the Act was the "broader federal effort during this period to rationalize and simplify policy governing the disposition of patent rights resulting from federally funded research" (Mowery et al.. 2004, 181). Notably, the Act didn't legalize anything that wasn't legal before. Instead, it removed the need "for universities to negotiate agreements with individual agencies or petition for patent rights on a case-by-case basis and reduced uncertainty about the direction of government patent policy" (Mowery et al.. 2004, 181).

4.3.1.2. Argued causal mechanisms and author findings.

Increased academic patenting and licensing had already begun many years prior to the Act's passage. Thus, Mowery et al.. argue that the Act's most important effect "was its provision of a congressional endorsement of patenting and licensing (including exclusive licensing) as appropriate activities for universities and public laboratories" (2004, 181). Many attribute (or blame) the growth of academic licensing and patenting to the Act, a generally used causal argument. However, Mowery et al.. found that the trend of patenting had already begun to grow steadily throughout the post-1945 period "with no break in trend after 1980" (2004, 181).

One of the causes (X) that affected the patent and licensing growth of the 1970s and 80s was advancements in basic science and particularly molecular biology (Mowery et al.. 2004, 182). The biomedical research growth during the 1970s and 80s grew on academic R&D infrastructure which had been receiving federal funding for biomedical science since the 1960s. Another cause was the decisions by the judicial and patent office "that clarified and broadened the range of patentable subject matter in the biomedical sciences" (Mowery et al.. 2004, 182). Notably, "no evaluation of the causes and consequences of increased university patenting since 1980 can overlook the influence of broader U.S. patent policy on such growth" (Mowery et al.. 2004, 182).

Mowery et al.. argue that their findings show that the Act did not have a dramatic effect on university patenting and licensing where universities already were active before the passage of the Act, like University of California or Stanford University (2004, 182). However, they did find that the Bayh-Dole Act "drew universities into patenting and licensing that previously had not been active in these fields". The new wave of entry into patenting and licensing was associated with "the production by many less experienced universities or relatively low-value patents". Entrants appeared to have learned over time how to obtain patents of greater economic and technological significance (Mowery et al.. 2004, 182).

Mowery et al.. analysis of U.S university patenting and licensing before and after 1980 show that these activities are concentrated in few research fields, specifically biomedical science (2004, 182). The biomedical field largely differs from other industries due to the unusual strength and economic value of patents in biomedical science. Moreover, molecular biology revolutionized the field during and after the 1970s, producing critical scientific discoveries used in the pharmaceutical industry. Mowery et al.. argues that this concentration of patenting and licensing in a narrow field of academic research "means that the effects of increased patenting before and after Bayh-Dole, on U.S. universities' "research culture" cannot be described as pervasive" (2004, 182). These effects are instead concentrated in a few areas of research and academic departments.

4.3.1.3. The Act and its true effect on university patenting and economic growth

Mowery et al.. asked the question "did the Bayh-Dole Act and the growth in university patenting that characterized the 1970-2000 period increase the contributions of university research to the "New Economy" in the United States in the 1990s?" (2004, 183). Here, the independent variable (X) is the Bayh-Dole Act. The causal mechanism, in this instance, is the growth in university patenting. This would then contribute to the increase of contributions of university research into the New Economy, which is the dependent variable.

To answer, the authors found the contributions of U.S universities to innovation and economic growth during the 1980s and 90s to be important. However, no evidence suggested that the contributions were more important then, than in the 30s or 50s (Mowery et al.. 2004, 183). Most importantly, they did not find any evidence that "proved" that the Act had "substantially increased these contributions or that any such expansion would not have

occurred in the absence of the Act". Instead, they found that the mechanisms for contributions made both before and after the Bayh-Dole Act are "complex and have included much more than patenting and licensing" (Mowery et al.. 2004, 183). Specifically, universities are good at quickly expanding new fields and techniques in science, as well as having close connections with external groups that benefit from their research. Mowery et al.. found that technology transfer does not depend on universities possessing intellectual property rights (2004, 184).

There was little evidence based on the claim of policymakers and university administrators that the Act had been an "unmitigated success and indispensable to the economic contributions by U.S. universities" (2004, 184). They exemplify this first by pointing out that the data on the growth of U.S. universities patenting and licensing activities alone provide no basis to conclude that "patenting and licensing are essential for technology transfer, since increased university patenting may cover technologies or inventions that previously were transferred via other channels". Second, they found that the types of growth others attribute to the Act such as increased academic licensing and patenting, and growth in university-industry collaboration predates Act. Lastly, they found that the "evidence" used on low rates of commercialization, such as the Harbridge House report, was weak (2004, 184).

Table 4.3.1.3. General causal arguments, and the alternative causal mechanisms and effects found by Mowery et al.

X – Cause and IV	**CM - Causal Mechanism**	**Y – Effect and DV**	
Act →	→ Increased university patents and licensing. →	Economy and innovation.	University contribution was important, but not more important during 80s/90s than the 30s/50s.
Act →	→Increased university patents and licensing.-->	More university research into "New Economy" during 1990s.	Evidence that such growth had begun decades prior to the enactment and was on a steep curve in the 70s due to the IPA agreements. Act is not the X.

Advancements of molecular biology→	Federal funding in basic and biomedical science in 1960s→Growth in 70s and 80s →	Patenting and licensing growth (in concentrated areas).	Alternative causal mechanisms and effects that authors found in their book.
Decisions by the judicial and patent office →	Made →decisions that →clarified and broadened → the range of patentable content in biomedical science. →	Academic patenting and licensing growth.	Alternative causal mechanisms and effects that authors found in their book.

Bayh-Dole supporters claim that the Act (X) has contributed to the unmitigated success and been indispensable to the economic contributions by U.S. universities (Y). However, the authors found little evidence for this causal mechanism. There was little evidence that expanded patenting and licensing of universities since 1980 have "produced significant shifts in the orientation of academic researchers away from fundamental research toward more applied, short-term research activities that might be more easily patented and licensed" (Mowery et al. 2004, 184).

Mowery et al.. found other possible causal mechanisms. For example, due to patenting and licensing being so concentrated in few areas, such a shift in academic research would itself be concentrated (Mowery et al.. 2004, 184). They also found that there was little evidence to suggest a shift in the research orientation of universities after Bayh-Dole, meaning that X would not necessarily have a big effect on Y (innovation by universities).

4.4. Economic Contributions of University/Nonprofit Inventions in the United States: 1996–2020 – AUTM

4.4.1. Introduction

The report for AUTM by Pressman et al., *Economic Contributions of University/Nonprofit Inventions in the United States: 1996-2020 – AUTM,* discusses research directly relevant to this thesis. The report uses survey data and an updated input-output estimation to model the

economic “impact of academic licensing” (Pressman et al.. 2022, 3). The model assumes “no detrimental product substation effects, and summing that impact over 25 years of available data from academic U.S. AUTM Survey respondents” (Pressman et al. 2022, 3).

This section will describe the report, the method used, and most importantly discuss the AUTM Survey data used to estimate economic effects of academic licensing. I will discuss the role of this report in the general study of Bayh-Dole. An important note is that the report does not directly relate the research to the Bayh-Dole Act. This is reflected in both the research and the AUTM internal survey; neither differentiates between patents and licenses that are subjected to the Act and not.

Yet, pro-Act lobby groups such as the Bayh-Dole Coalition cite this report and its older predecessors in arguments for the Act's success (Bayh-Dole Coalition). In a 2021 memo, the Coalition cited an AUTM infographic as the source for the Act's $1.7 trillion contribution to the U.S. economy (Bayh-Dole Coalition 2021, 5) (AUTM 2018). Thus, although the report does not specifically mention the Act, its use in Act success arguments is a good reason to include it in studies of the Act’s macroeconomic outcomes.

4.4.2. AUTM and the AUTM report

AUTM (Association of University Technology Managers) was known as “Society of University Patent Administrators (SUPA)” when created in the mid-1970s (AUTM n.d.[A]). AUTM heavily lobbied through the Bayh-Dole Act prior to the Act’s passing as SUPA (WARF n.d.). Norman Latker was the creator and writer of the Bayh-Dole Act and later Reagan’s 1983 memorandum, which allowed large for-profit corporations to retain title to federally funded inventions (Latker n.d.). Latker was also a founding member and contributor of SUPA, “working with the founders of what became AUTM” to create the Act (Bayh-Dole Coalition n.d.). Today, AUTM define themselves as the “non-profit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward” (AUTM n.d.[B]). AUTM comprises “more than 3,000 members who work in more than 800 universities, research centers, hospitals, businesses and government organizations around the globe”.

It is important to note that AUTM is an interest organization that lobbied for the Bayh-Dole Act in the late 1970's, and Latker, their founding member, drafted the Bayh-Dole Act (Latker n.d.). AUTM exists to continue to fuel technology transfer, and specifically, to fuel the use of patents (AUTM n.d.[A]). SUPA, along with others, argued prior to the Acts enactment that patents would fuel incentive to innovate, and thus commercialize these inventions (WARF n.d.).

AUTM developed their own impact model in the mid-1990s, that included measures "of preproduction impact, using i) royalties and an assumed royalty rate to estimate licensees' sales, and ii) Census Bureau data on salaries at technology companies to estimate jobs supported by licensing activities" (Pressman et al. 2022, 6). The estimates were published in the AUTM Survey in the mid and late 1990s.

4.4.3. The AUTM Survey data

The AUTM Survey nonprofit licensing data used in the study was originally gathered by AUTM members for internal use, and "only later used to help describe the impact of their technology transfer activities outside their home institutions" (Pressman et al. 2022, 6). The Survey began in 1995 as a practitioner-generated survey instrument. The data reported is usually from named institutions, with varying percentages of respondent rate; in 2022 the respondent rate was sixty-three percent (Pressman 2022, 20). Although the AUTM Survey tracks federal and other types of funding, it does not track metrics which would estimate the outcome of the Act. For example, it does not differentiate between subject inventions and normal inventions (AUTM 2022). Thus, it cannot estimate the creation of American jobs created by the domestic manufacture of subject inventions.

In 1998, a GAO report to the Congressional Committees on the "Administration of the Bayh-Dole Act by Research Universities" discussed the 1996 AUTM survey and evaluated the legitimacy of the Survey (GAO 1998):

> The AUTM survey is limited in its application to Bayh-Dole R&D because the survey covers the activities involving inventions by the universities from all funding sources—not just federal. Also, the AUTM survey is limited as an evaluation device in that (1) the data are based on a survey sent to the organizations, (2) not all organizations respond, (3) respondents report data according to their own fiscal year,

and (4) no independent verification or validation of the data is provided. The AUTM report states that "[T]he information contained in the Survey reports is best used as a starting place or as a point of departure for more extensive analysis (GAO 1998, 15).

The 1996 AUTM survey found that the economic contributions of academic licensing were extensive. The GAO report did not verify the "accuracy of the model or the projections made by AUTM for economic impact, nor did we attempt to determine what portion of this impact was attributable to Bayh-Dole". Most importantly, GAO found that the underlying data was based on unverified information reported on a survey. The 2022 survey does not measure Act specific metrics, nor economic contributions of subject inventions. As such, the 1998 critique of the AUTM Survey is still relevant.

4.4.4. Estimation model used – Input-Output model

The report uses an updated Input-Output quantitative model. The model "represents the interdependencies between different sectors of a national economy or different regional economies" (Pressman et al.. 2022, 5). Further, it takes microeconomic data, their internal, annual survey data that reports "license income and running royalty income reported in the annual AUTM survey" (Pressman et al.. 2022, 5)..

The authors combine the AUTM data with "empirically documented patterns of transaction in the U.S. economy" witch estimates "AUTM Survey respondents' and their licensees' contribution to the U.S economy using standard economic metrics: gross domestic product (GDP), gross output (GO), and jobs" (Pressman et al.. 2022, 5). In order for the authors to "apply these macroeconomic empirical generalizations", they have to make assumptions "about the types of products made and sold by AUTM licensees, where the products are made and how they are subsequently used or transferred" (Pressman et al.. 2022, 5).

The model primarily relies on "impacts arising from sales of licensed products", which is needed to estimate the sales (Pressman et al.. 2022, 5). The AUTM Survey reports the royalties earned on product sales, but not the sales themselves. They then estimate the "dollar value of licensees' product sales" by "assuming a weighted average running royalty rate, and using the available running royalty information". The model used and described in the report "describe the economic impact of nonprofit technology transfer activities using standard

economic metrics: GDP, GO, and employment" (Pressman et al.. 2022, 5). The model used in the report is based on the economic impact model using standard economic approaches.

4.4.4.1. Model assumptions used and how it measures academic licensing and patenting

The authors used two variations of model assumption (Pressman et al.. 2022, 17). One for the general estimation, and another for domestic production. To assume domestic production, the production "is by large entities, and that the domestic production of large entities can be modeled by knowing the non-domestic employment of U.S. majority owned multinational enterprises by industry, and the total employment of enterprises in the same industries" (Pressman et al.. 2022, 17). Most importantly, "the fraction of products made domestically is inferred from BEA data on foreign employment by industry combined with Census Bureau data on the domestic employment of the same research-intensive industry".

Despite using quantitative data to assume the domestic production of licenses, the authors admit in the "Table A-1: Complex model assumptions and effects" that they do not have data on the manufacturing location of licensed products (et al. 2022, 32).

4.4.5. Research results found in the study

Pressman et al. found that the contributions of "academic licensors to industry gross output range from $631 billion to $1.9 trillion, in 2012 U.S. dollars" (Pressman 2022, 3). The contributions to "gross domestic product (GDP) range from $333 billion to $1 trillion, in 2012 U.S. dollars". Results showed that the estimated "total number of person years of employment supported by licensed-product sales range from 2.356 million to 6.499 million over the 25-year period" (Pressman 2022, 3). The authors note that "better information on the actual industries of the licensed product and where they are made and for what use would also be helpful" (Pressman 2022, 29). According to the estimation model used with the internal AUTM survey data, the economic impact of academic licensing and patenting ranges from high to significantly high.

4.5. Chapter conclusions: Unbiased research is necessary for nuanced policy evaluation

In this chapter I have discussed two important contributions to the study of the Act: the *Ivory Tower and Industrial Innovation: University – Industry Technology Transfer before and after the Bayh-Dole Act* and the *Economic Contributions of University/Nonprofit Inventions in the United States: 1996-2020 – AUTM.*

I argue that the *Ivory Tower and Industrial Innovation: University – Industry Technology Transfer before and after the Bayh-Dole Act* is still one of the most considerable contributions to the research on the Act. Despite being published in 2004 it contributes important insights on the argued CMs of the Act on innovation. This is essential for proper policy evaluation of the Act.

To quickly sum, Mowery et al. found that the role of Bayh-Dole has been exaggerated in the debate on the Act's contribution to innovation and economy and that its effects could not be described as "pervasive". Specifically, they found that patenting and licensing activities both before and after 1980 were concentrated in a few fields (Mowery et al.. 2004, 182). Further, they found that the economic contribution from universities had mostly relied on other channels than patenting and licensing (Mowery et al.. 2004, 179). Much of the debate during the hearings prior to the enactment of the law surrounded the causal argument that patents (X) are crucial to, and induce, innovation (and commercialization, Y). Mowery et al.'s research found that this is not necessarily correct and that there are potentially other, more significant causal mechanisms for this innovation.

The AUTM report contributes with recent research on the Act's macroeconomic consequences. This is also research important to the evaluation of the Act. However, AUTM is an interest organization and heavily lobbied for the Act's passage. The writer of the Act is Norman Latker, a founding member of SUPA (early days AUTM). Latker wrote President Reagan's 1983 memo to allow large for-profit corporations to receive title to federally funded inventions. The 1980 Act did not allow this, as it was focused on lifting small business to equal footing of those large corporations due to fear of corporations having an economic monopoly of federal funding.

AUTM is dependent on the Act to not only survive, but be successful and profitable. If patenting and technology transfer is profitable, this gives cause for AUTM to continue to receive funding and to keep business open. To survive, AUTM needs the facilitation and use of licenses and patents. To reiterate, AUTM has actively had a hand in the creation of the Act and I therefore argue it has the motive to make the Act seem successful. It is then reasonable to argue that the Survey data AUTM bases the report on to be biased research.

The GAO report from 1998 confirms that the 1996 survey data AUTM is unverified. Further, no information available indicates that the 2022 Survey is any different. Most importantly, the Survey in both 1996 and 2022 do not differentiate between licenses and patents subjected to the Act and those that are not. This is crucial for precise policy evaluation. This means that the report also does not estimate the economic impact of Act subject invention licenses. This then begs the question, why does the Bayh-Dole Coalition use a report that cannot estimate specific Act outcomes as proof of Act success? Although this question extends the scope of this thesis, it is important to note when providing a nuanced overview of Act research, especially since AUTM's research is the only so far that covers those specific economic consequences of the Act.

5. Theoretical background and framework for this thesis

5.1. Introduction to this chapter

This chapter details the theoretical framework of this thesis and makes sense of the Act's mechanisms for causality. I will first present and discuss the pro/con arguments of patent policy change found in the hearings held prior to the Act. These arguments explain the general theorized causal mechanisms (CM) that argue for the legislation prior to enactment and how it would affect innovation. Innovation was one of the main concerns when passing the Act. I then present the main arguments found that argue against Bayh-Dole-like legislation and refute several of the argued and theorized CMs.

Second, I will discuss the Bayh-Dole Act and its relation to manufacturing. I present the only found causal mechanism in hearings held on the Act the last year prior to enactment. This only found CM theorizes how the Act 204 manufacturing provision would have an effect on domestic manufacturing.

Third, I will present and discuss the general theory behind the Bayh-Dole Act (Act) to provide a nuanced overview and understanding of the concepts and theories presented and discussed in the earlier section.

5.2. Arguments used during hearings prior to the enactment of Act in 1979 AND 1980

5.2.1. Introduction

In this subsection I recount some of the most commonly used arguments during the hearings prior to the enactment of the Act. These arguments and other sources of arguments will be used to explain the causal mechanisms that advocate for the Act.

I will first present and discuss the arguments found in favor of the Act. This section will recount the most used arguments for why and how a patent policy change would have a positive effect on the economy. I included the opening statements of Senator Bayh and Dole, who were co-sponsors of the Act. Further, I identify and sum up the main causal mechanism (CM) found in the arguments for how a change in patent policy/patent legislation and thus patents (X) will increase innovation (Y). Second, I will present and discuss the common arguments found in the hearings that argue against the Act and BD-like legislation. As the first section showcases and summarizes the causal argument and the general causal mechanism, the second section presents the arguments that refute some of the causal claims reiterated in the first section.

Lastly, I present the only found causal mechanism in hearings held on the Act the last year prior to enactment.

5.2.2. Pro-Bayh-Dole arguments and causal mechanisms

In the opening statements of Senator Bayh and Dole during the hearings on the Act, Bayh and Dole stated (96 U.S. Congress, Senate, Committee, S. 414, 1) (96 U.S. Congress, Senate, Committee, S. 414, 28):

> Senator Bayh: I have become very concerned that the United States is rapidly losing its preeminent position in the development and production of new technologies,

which historically has been our strong suit. Some examples of this disturbing trend are the following facts: Importation of foreign manufactured goods are second only to foreign imported oil as the biggest drain on U.S. dollars.

Senator Dole: The effect of this policy is twofold, bearing on the consumer as well as on the economy in general. In both cases, the public is the victim.When large amounts of taxpayers' money are directed to the research field, the public expects and deserves to reap the benefit of its investment in the form of products available for its consumption. When this fails to materialize, it is obvious that the Government has reneged on its promise. This is evidenced by the fact that, of the 28,000 inventions funded by the Government, only about 5 percent have been used.

Senator Bayh and Dole's opening statements sum up the majority of arguments for why there was a need for patent policy change. The arguments presented below are all from the Senate hearings on patents, small businesses and innovation during 1979 and 1980. They are taken from the hearings on the Bayh-Dole Act (Act),

It was argued during the hearings that the public interest is at the core of the patent system, as inventions are of little value until they are utilized by society (96 U.S. Congress, Senate, Committee, S. 1215, 245-262). While the patent system was created as an incentive for research and development for public benefit, it was argued that it was no longer achieving this objective. The argument was then that the public interest demanded that inventions be utilized efficiently and in a manner that promotes healthy competition.

5.2.2.1 The general causal argument

The arguments used for transferring patent rights from the public to the private sector all echo in some way or another the same basic points. Mainly, that by giving the patent (X) rights of federally funded research to the organization or company that did the research would create an incentive for them and other organizations or companies to participate in FFR and design (96 U.S. Congress, Senate, Committee, S. 1215) (96 U.S. Congress, Senate, Committee, S. 414). This would in turn fuel innovation through the creation of new research and products, which would increase the rate of commercialization of FFR which has a positive impact/effect on innovation (Y) (96 U.S. Congress, Senate, Committee, S. 1215) (96 U.S. Congress, Senate, Committee, S. 414). This would allow the private sector to increase the

rate of commercialization more than the government which was argued to be at about 5 percent. As such, economic benefits like profit, job creation, economic growth, competition and more would follow.

The summary of arguments and causal mechanisms include the accompanying discussion of the issues that were seen as implications to innovation and the innovate-like structure of the U.S economy. For example, Senator Bayh argued that the decline in American innovation and productivity at the time posed a great threat to the economic and political well-being of the U.S. (96 U.S. Congress, Senate, Committee, S. 1215, 458). Further, the at-the-time patent policy was identified as the contributing factor to this decline. This then affected the most innovative segment of the economy–small businesses. It was argued that government patent policy had become a barrier to increased competition, entrepreneurship, and denying or delaying potentially important medical discoveries to suffering patients (96 U.S. Congress, Senate, Committee, S. 1215, 459).

Small businesses were the solution to this line of argumentation. Specifically, it was found that small businesses had made over half of the most important inventions since WWII and were the leading source of new jobs (96 U.S. Congress, Senate, Committee, S. 1215, 459). They thought the denial of patent rights to important inventions derived from federal funding occurred prior to the Act, and this would be a disincentive for small businesses to participate in federally funded R&D. This would in turn hurt innovation and the creation of more federal research and commercialization (96 U.S. Congress, Senate, Committee, S. 1215, 459)

5.2.2.2. The Impact of Patent Policy on Innovation, Productivity, and Small Businesses and how patent rights rectify these impacts.

One of the goals of the Bayh-Dole Act was to lift small businesses and research organizations to a more equal standing of large, for-profit corporations which were argued to receive a larger percentage of federal funding. The reason was that small businesses were found to have played a vital role in the growth and innovation of the economy (96 U.S. Congress, Senate, Committee, S. 414, 230). Further, they were found to have been a source of new jobs for the decade prior to the Act of 1980 (96 U.S. Congress, Senate, Committee, S. 414, 230). However, the patent policy at the time was argued to be a hindrance to small business and the

economy's growth and innovation, despite their usefulness to the U.S. economy (96 U.S. Congress, Senate, Committee, S. 414, 230-231).

By allowing small businesses to obtain patent (X) rights on research created with federal funding and allowing them to commercialize the product, greater product innovation (Y) would be achieved in the American marketplace (U.S Senate, Committee on the Judiciary, first session on S.414, 1979, 230-231). The lack of patent rights (X) acted as a disincentive for many small companies to participate in the federal R&D process, resulting in a decline of private sector innovation (Y) during the 1970s. Further, the current patent system was viewed as un-innovative and seen as working to the advantage of foreign firms at the expense of American industry and labor (96 U.S. Congress, Senate, Committee, S. 414, 261). A uniform patent policy would allow small businesses to participate in federally funded R&D without being disadvantaged (96 U.S. Congress, Senate, Committee, S. 414, 230-231).

Innovation was considered the driving force to real economic growth with the introduction of new products and services to the economy, increased process productivity, and increased exports, strengthening the currency and increasing productivity marketplace (96 U.S. Congress, Senate, Committee, S. 414, 231) (96 U.S. Congress, Senate, Committee, S. 1215, 264). The introduction of new products into the economy through innovation was seen as critical to long-term economic growth and job expansion (96 U.S. Congress, Senate, Committee, S. 1215, 264) (96 U.S. Congress, Senate, Committee, S. 414, 190).

Many examples were used to highlight the importance of innovation, such as the cotton gin, steamboat, railroads and telecommunications (U.S Senate, Committee on the judiciary, first session on S.414, 1979, 230-231). Interestingly, these are also innovations Mazzucato attributes to the State (Mazzucato 2013). The Bayh-Dole Act was introduced to address the issues of the at-the-time patent policy, giving patent rights to the private sector to create confidence in the patent system, to cut down on bureaucracy, and to encourage private industry.

Another argument for the Act was that the at-the-time patent policy was denying American taxpayers the fruits of their investment (96 U.S. Congress, Senate, Committee, S. 1215, 458). It was therefore in the best interest of the citizens to give patent rights to the private sector. The argument was that giving patent (X) rights to the private sector would encourage

private industry and thus innovation (Y). Again, it was argued that the at-the-time patent policies had fostered concentration in relatively few firms, depriving the most innovative segment of the American economy. The answer was to lift small businesses by passing a legislation that would only allow small business and research organizations to receive title to patents created with federal funding. Small business and research organizations were singled out because they were found to be crucial to the fight against inflation and unemployment and generated tax revenue at a higher rate.

5.2.3. Arguments that argue for how a change of patent policy will negatively affect the economy

5.2.3.1. Admiral Rickover and private vs public patent ownership

One of the biggest opponents to allowing the private sector to patent FFR was Admiral H. G. Rickover. Admiral Rickover testified at several hearings on patent issues, and strongly opposed any transfer of rights of patents from public ownership (96 U.S. Congress, Senate, Committee, S. 1215, 172). He stated that the original purpose of patents was to promote the public interest by expanding the nation's industry, economy, and trade (96 U.S. Congress, Senate, Committee, S. 1215, 172).

In 1979, the development of patents generally involved large organizations and corporations, rather than individuals developing single items. General Rickover argued that granting legal monopolies to contractors in exchange for Government funded inventions would be abandoning a free competitive enterprise system (96 U.S. Congress, Senate, Committee, S. 1215, 172).

Those who were pro-Act like legislation argued that the public would be protected against misuse by "march-in" rights (96 U.S. Congress, Senate, Committee, S. 1215, 172). However, General Rickover found the "march-in" rights to be a cosmetic safeguard and would not offer real protection to the public. He explained that implementing a provision like "march-in" would require a large government bureaucracy to receive, review, audit, and act upon contractor reports throughout the life of each patent. With over 30,000 unexpired patents at the time of the hearing, it would be challenging for the Government to track contractor activity (96 U.S. Congress, Senate, Committee, S. 1215, 172).

During General Rickover's time working with government research, he observed that the vast majority of patents, even in the nuclear industry, were of little or no significance (96 U.S. Congress, Senate, Committee, S. 1215, 172). For example, he found that large corporations would often file numerous patents that were not new inventions but rather small changes or updated design features. Additionally, such filings were often made to discourage competitors, potential competitors, or small firms in the market. As not many firms are either able or willing to take on the associated cost, and most patents contested in court are ruled invalid. General Rickover argued that patents were likely to discourage competition (96 U.S. Congress, Senate, Committee, S. 1215, 172).

5.2.3.2. Statement of Hon. Russel B. Long, U.S. Senator from Louisiana

Senator Long was also one of the most vocal opponents of a patent policy change like the Act. Like Admiral Rickover, the Senator participated in the numerous hearings held on the subject. He argued that patents that were created with federal funding should stay in the public domain (96 U.S. Congress, Senate, Committee, S. 1215, 463). For example, he thought that the rights resulting from Government R&D could "increase monopoly and the concentration of economic power" (96 U.S. Congress, Senate, Committee, S. 1215, 463).

The original purpose of research and development was to ensure that no research would be "contracted for, sponsored, cosponsored, or authorized under authority of a particular piece of legislation unless all information, uses, products, processes, patents, and other developments resulting from such research will be available to the general public". In fact, Senator Long called the patent right giveaway the "greatest giveaway in our history" (96 U.S. Congress, Senate, Committee, S. 1215, 463).

Another point Senator Long made was how information on these inventions would become secret once the contractor is given monopoly rights (96 U.S. Congress, Senate, Committee, S. 1215, 464). Information on how the results are being used, how much money it makes and more would be removed from public view. Not only would the contractor get a seventeen year monopoly, but the public would also not be able to see to what extent the results are being exploited by "unjustifiably high prices or other restrictive measures" (96 U.S. Congress, Senate, Committee, S. 1215, 464).

Traditionally, patents have been used as an incentive for private persons that are willing to take the risks to reap the rewards, to "promote the progress of science and useful arts". However, they were "never intended to reward persons who perform research at someone else's expense as part of a riskless venture" (96 U.S. Congress, Senate, Committee, S. 1215, 464).

Extensive hearings held by the Senate Small Business Committee's Monopoly Subcommittee during the chairman tenure of Senator Long and Senator Nelson, all inevitably came to the same conclusion; "the provisions of S.1215 and similar bills (S.414 for example) are deleterious to the public interest" (96 U.S. Congress, Senate, Committee, S. 1215, 464). An extensive list of witnesses included acclaimed economists, "a Deputy Attorney General of the United States, an Assistant Attorney General in charge of the Antitrust Division of the Justice Department, two Chairmen of the Federal Trade Commission" and more. All witnesses testified that private company financing of research and development is risk-taking, and as such deserves the fruits of that risk. However, "Government research and development contracts (…) are generally cost-plus with an assured market – the U.S. Government". As such, there would be no reason for the taxpayer to be forced to "subsidize a private monopoly and have to pay twice: first for the research and development and then through monopoly prices" (96 U.S. Congress, Senate, Committee, S. 1215, 464).

In 1977, the Assistant Attorney General, John H. Shenefield, for the Antitrust Division, Department of Justice and Michael Pertschuk, Chairman of the Federal Trade Commission stated that there was "no factual basis for the claims that giving away title to private contractors promotes commercialization of government-financed inventions and that the available evidence shows just the opposite" (96 U.S. Congress, Senate, Committee, S. 1215, 464). They also stated that proposals such as "march-in rights" would be "ineffective and valueless to protect the public against patent misuse" (96 U.S. Congress, Senate, Committee, S. 1215, 465).

At a hearing in 1977, Stanley M. Clark testified that "I believe in free enterprise and in a competitive system. But the proposal that the Government spend large sums of money for research and development and then hand the patents stemming from such research over to the private contractors is not consistent with free enterprise" (96 U.S. Congress, Senate, Committee, S. 1215, 465). Allowing contractors to retain patent rights would both promote

monopoly and concentration of economic and political power, as the largest corporations do most of the government research (96 U.S. Congress, Senate, Committee, S. 1215, 465).

5.3. 204 "manufactured substantially" provision

The analysis of the 204 provision (then titled section 205) was the only found causal mechanism in historical records on the Bayh-Dole Act. In fact, it was one of the few mentions of manufacturing at all. In a section-by-section analysis by Senator Bayh for the "University and Small Business Patent Procedures Act" S.414, Senator Bayh explains the purpose of the 204 provision, titled "preference for United States industry":

> section 205 provides that persons receiving exclusive licenses to use or sell a subject invention in the United States must agree to manufacture any products embodying the invention substantially in the United States. Agency approval is required to dispense with this requirement. This section is designed to maximize the probability that the jobs created through the commercialization of new products and technologies based on Government supported inventions will benefit American workers (96. U.S. Congress, Senate, Committee, University and Small Business Patent Procedures Act, 34).

The argued causal mechanism between the Act and domestic manufacture of FFR is simply laid out by Senator Bayh. By having section 204 (X) provide that persons receiving exclusive licenses must agree to manufacture any products embodying the invention substantially in the United States (Y). This will create jobs through the domestic manufacture of FFR and thus benefit American workers.

This causal argument or link is rather simple. It does not explain all the activities that an actor does in order for X to have an impact on Y. The vagueness of the provision is the provisions biggest weakness and concern. If one reads through Bayh's analysis on all the other provisions of the law, there is thorough analysis of the cause and effect of each provision. Despite domestic manufacturing being an explicit goal of the Bayh-Dole Act of 1980, there is little historical record of this being a larger issue either during hearings, reports or Bayh's analysis. Therefore, this is the causal mechanism between X and Y that I identify in this thesis, presented by Senator Bayh. In Chapter Six, the method section, I take this identified causal mechanism and complete it to a fully developed causal mechanism.

5.4. General theoretical framework

The Act is based on the assumption that patents are the drivers and cause of innovation. Therefore, a theoretical framework that provides a nuanced picture of the theorized why is essential. Although this thesis researches domestic manufacturing, the public vs. private debate surrounding patents is the original source of this issue. Further, there were many claims regarding the state, the patent law, and its use for the public interest. For example, it was claimed that the patent policy pre-Bayh-Dole caused economic monopoly as it favored big firms (96 U.S. Congress, Senate, Committee, S. 1215, 249). This section seeks to provide a nuanced overview of the theoretical framework behind these claims, as well as other central theories that refute these claims.

The first theoretical claim was patents and their role in creating a monopoly. The theory of patents and monopoly is relevant to the Act, as economic monopoly was theorized to be the outcome of a change in patent policy, like the Act (96 U.S. Congress, Senate, Committee, S. 1215, 172) (96 U.S. Congress, Senate, Committee, S. 1215, 463). At the same time, it was claimed that the pre-Act patent policy was causing economic monopoly and that the Act would remedy this (96 U.S. Congress, Senate, Committee, S. 1215). Monopoly is the opposite of competition, yet, competition was another heavily used argument for why a patent policy change was needed for small businesses. In this section, I present and discuss *What is a patent?* by Hamilton and Till.

The second, innovation theory, is the theory that explains the general argument that patents are needed for innovation. When reading through the congressional hearings for the Act and the Act's unsuccessful predecessors, different types of innovation theory were the most used. This provides the theoretical framework behind the debate and these specific arguments.

Additionally, I discuss the theory of Mariana Mazzucato in *The Entrepreneurial State*. Many of the arguments used for patent policy change is that the government is both bad at innovation and commercialization, along with other ideologically loaded arguments. In her book, Mazzucato argues against these beliefs and myths coupled with facts. This provides a more nuanced picture of the debate of public vs private sector on innovation, and the relationship between the public and private sector in creating R&D.

The third theory is the evaluation and measurement of Bayh-Dole using an expanded set of public values instead of measuring the Act in terms of innovation. In addition, this is explained in the backdrop of neoliberalism which has had a strong effect on innovation policy during the time Act was enacted and after.

5.4.1. Hamilton and Till on monopoly and its relation to patents

In 1941, Walton Hamilton, a Yale professor and Special Assistant to the Attorney General wrote a document for the government on issues with the patent system (Barnett 2021). This document was part of a larger study by the Senate on the concentration of economic power. The issue of concentrated economic power became important in the debate between Vannevar Bush and Senator Harley Kilgore over how federal funding for science should be distributed (Barnett 2021).

A few years later Hamilton and Irene Till, an economist who worked for many years in various federal agencies, wrote *What is a patent?* (1948). The article discusses what patents are, how they work, and how patent policy change affects the political economy. Hamilton and Till argue that the use of exclusive licenses is "dangerous business" (Hamilton and Till 1948, 247). Patents are inherently a monopoly which interferes with the "system and antitrust acts that "decide" that the industrial system shall operate as a free enterprise". As Hamilton and Till explain, "A monopoly removes from the domain of competition all that it encompasses. If the monopoly can be enlarged and perpetuated, it threatens to remove areas of industry from market control and to make of them closed corporate estates." (1948, 247).

Hamilton and Till distinguish the patent from the invention (1948, 253). By using the example of the safety razor; they ask if it is one whole invention, or made up of several different inventions? Furthermore they ask: is there one patent to be filed, or 20, or even two hundred? Is the inventor responsible for this one, big idea, or did they "merely take an all-but-obvious step?" (1948, 253). Is it the way to shave that's the invention, or does the invention lie somewhere within the parts used?

Using this analogy, the authors argue that unless the invention has a "clear-cut identity", a patent should not be issued. This was not the procedure of the Patent Office at the time. If it

"acted solely upon the injunction to advance "the progress of science and useful arts", they would isolate the advance before blessing it with a patent" (Hamilton and Till 1948, 254). Furthermore, the Patent Office "assumes that an invention claimed is an invention made-unless disproved" which "patrons" take advantage of (Hamilton and Till 1948, 254). Hamilton and Till state that "it is the very purpose of the patent lawyer to flood the office with an endless stream of applications".

Hamilton and Till argue that the patent lawyer is a large actor in expanding the scope of the patents of their clients (Hamilton and Till 1948, 254). They use the example of the Ethyl Gasoline Corporation who "took out a single patent on the Midgley process for combining gasoline with tetraethyllead. Then, to entrench this patent in a strategic position, a host of applications were filed". They filed subsequently three different patents on different variations of the same invention, then a group of five patents on other variations. There were four patents on another variation as well, in addition to a group of eight patents, all granted on the same day, which covered different variations of another patent. The strategy is outlined; the goal "was to exclude all inventions (…) in a field of use dominated by a single simple idea".

They further point out that the defined boundaries of a patent are blurred (1948, 256). And if it is "desirable that the inventor secure an exclusive right to his invention, it is equally essential that his privilege shall not trespass upon what is not his" (Hamilton and Till 1948, 256). Meaning, the inventor does not have the claim to prior inventions or scientific discoveries nor technology around them. Through the condition of their grant, their contribution should be sharply separated from everything related. Unless these steps are taken, "the patent owner may assert a private claim to some part of the fund of common knowledge; he may assert a monopoly over techniques which all members of the industry are legally free to use" (Hamilton and Till 1948, 256).

5.4.2 Innovation theory

Introduction

The first theory in this subchapter is general innovation theory by Richard D. Nelson and Roberto Mazzolini from Columbia University. They provide a broad overview of the main types of innovation theory which discuss the "principal costs and benefits of patents and

discuss assumptions about the contexts in which inventions are made or developed" (Nelson and Mazzoleni 1996). The authors explain that context is important for innovation theory, as different patents "play different roles in different technologies and sectors". In some contexts patent theories "have a degree of plausibility; in others, none of them are very plausible" (Nelson and Mazzoleni 1996).

Fritz Machlup reviewed in 1958 "how economists view the patent system" (Nelson and Mazzoleni 1996). Machlup found that economists were generally negative to the societal value of the patent system, "reflecting their concern that patents generate monopolies and that, in many cases, patents are not even necessary to encourage invention". His own views were however that "it serves some useful purposes" (Nelson and Mazzoleni 1996). The three types of innovation theories presented below are the invention-inducement theory and the development and commercialization theory.

Invention-inducement theory

The invention-inducement theory is explained as "the anticipation of receiving patents provides motivation for useful invention" (Nelson and Mazzoleni 1996). This the most familiar theory on patents, and reflects many of the arguments used during the Congressional Hearings for patent policy change. Much of the discussion surrounding the benefit of patents was that the only social use of patents was to motivate useful inventions and that "patents always serve this purpose" (Nelson and Mazzoleni 1996). However, the authors find the situation to be more complex. All versions of this theory presume "either that if there is no patent protection there will be no invention, or more generally, that without a patent system incentive for inventions will be too weak to reflect the public interest" (Nelson and Mazzoleni 1996).

Inventors are usually "assumed to be diverse, working on different and generally noncompeting things" (Nelson and Mazzoleni 1996). As such, "in the absence of redundant efforts that might occur if many groups worked on competing things", stronger patent protection results in a larger number of useful inventions. In addition, strong patents would then provide the incentives to invent "for parties who are limited in the extent to which they can use the invention themselves, by facilitating the sale of rights to an invention" (Nelson and Mazzoleni 1996). Stronger patents may increase invention inefficiency in fields where patent protection leads to a larger flow of valuable inventions (Nelson and Mazzoleni 1996).

Under the invention-inducement theory, it is presumed that offering or granting a patent is not in the social interest if it is not necessary to induce an invention.

It is generally assumed in most versions of the theory that the "social benefit of a particular invention is strictly its final use value" (Nelson and Mazzoleni 1996). The social benefit of patent protection therefore stems "from the additional invention induced by the prospect of a patent". The social cost is then "the restriction on the use associated with the monopoly power lent by a patent". (Nelson and Mazzoleni 1996).

It is debated whether or not patents are an imperative incentive for encouraging innovation. Empirical evidence shows that patents are only an important part of the inducement for invention in a small number of industries among firms engaged in R&D (Nelson and Mazzoleni 1996). Patents were found to be much less important in industries such as electrical equipment, primary metals, instruments, office equipment, and motor vehicles. However, the pharmaceutical industry reported that without patent protection, 60% of their new pharmaceuticals would not have been developed. For inventors who must sell or license their inventions for returns, patents might be far more important. Therefore, according to Nelson and Mazzolini, patents are in some sectors an essential part of the inducement for inventing (Nelson and Mazzoleni 1996).

Development and commercialization theory

Development and commercialization theory can be summed as "patents induce the investment needed to develop and commercialize inventions" (Nelson and Mazzoleni 1996). The theory in its simplest version is derived from the invention-inducement theory where patenting occurs "early in the process of inventing and with much additional work needed before the "crude" invention is ready for actual use" (Nelson and Mazzoleni 1996). In the early stage, a patent is seen as providing an assurance of economic rewards if the development is "technological successful". This induces a decision to develop the patent and "the possession of a patent enables the patent holder to go to capital markets for development financing" (Nelson and Mazzoleni 1996).

Another difference between the two theories is when an organization “does the early inventing work but is not in a position to do the development work” (Nelson and Mazzoleni 1996). The original inventors “possession of a patent then facilitates handing off the task to an organization better suited for development and commercialization”. For example, General Electric in the 1920’s bought and developed many inventions made by small firms or private inventors (Nelson and Mazzoleni 1996).

The development and commercialization theory was widely used and cited in the discussions and hearings leading up to the passing of the Bayh-Dole Act (Nelson and Mazzoleni 1996). It was argued that despite public funding, patents had no economic purpose until they were developed to commercialization. In addition, "only companies were able to undertake such development”. Under the version of the theory most used in the Act discussion, “a company would be unlikely to engage in development of a university invention unless it held proprietary rights” (Nelson and Mazzoleni 1996). As well, “if universities held strong patent rights, they would be in a position to sell exclusive licenses”. In contrast, if the government held patents with nonexclusive licensing “companies would be unlikely to invest in the necessary development work” (Nelson and Mazzoleni 1996).

5.4.2.1. Mariana Mazzucato and the Entrepreneurial State: Debunking Public vs. Private Sector Myths

Mariana Mazzucato is an award-winning professor in the Economics of Innovation and Public Value at University College London (UCL), where she is Founding Director of the UCL Institute for Innovation & Public Purpose (IIPP)” (Mazzucato n.d.). In *The Entrepreneurial State: Debunking Public vs. Private Sector* Mazzucato argues the true role of the State in innovation and dispels old myths that find the State old and un-bureaucratic.

The State has in many parts of the world been going through a massive withdrawal. By decreasing the State’s involvement in the economy to reduce debt, the State is to become more “competitive” and “innovative” (Mazzucato 2013, 14). As businesses are being viewed as the driving force of innovation, the State is being seen as both bureaucratic and slow-moving (Mazzucato 2013, 14). In order to defend the State’s existence and size, it’s important to highlight the potential innovative and dynamic character of the State. Mazzucato argues that the State can play an entrepreneurial role in society by investing in large,

visionary projects that private businesses may not have the resources for or willingness to pursue (2013, 16). She further exemplifies this by using examples from government funded projects and inventions such as the Internet, Apple, GPS, touch-screen display or even SIRI voice activated personal assistant.

Mazzucato argues that the State needs to be viewed as more than just a facilitator of economic growth (Mazzucato 2013, 17). Instead, it should be seen as a key partner of the private sector, one that is willing to take risks that businesses won't. The State should not be swayed by interest groups seeking handouts and unnecessary privileges but should work dynamically with them to promote growth and technological change (Mazzucato 2013, 17).

Shrinking of the State and innovation

The shrinking of the State is based on the notion that if the government shrinks, private businesses will become more innovative and entrepreneurial (Mazzucato 2013, 25). The media, businesses, and libertarian politicians all draw inspiration from this idea and argue that the private sector is dynamic, innovative, and competitive, while the public sector is "sluggish, bureaucratic, and inertia" (Mazzucato 2013, 25). Despite this, the government has played a crucial role in the development of railroads, aircraft, space and aircraft industries, agricultural research, life sciences and much more (cite).

The State attempts to innovate at a much more difficult level than private businesses (Mazzucato 2013, 28). Public venture capital "is willing to invest in areas with much higher risk, while providing greater patience and lower expectations of future returns" (Mazzucato 2013, 28). The State is also at fault for perpetuating myths by not taking proper credit for its role for winning projects (Mazzucato 2013, 28). Further, the State has reduced to being timid and vulnerable, especially to the "capture" of "lobbies seeking public resources for private gain" (Mazzucato 2013, 28).

Lobbying efforts by the US venture capital industry in the late 1970s successfully reduced capital gains taxes, even though they depended on government funding for their success (Mazzucato 2013, 28). Venture capital industry was able to lobby and convince the state that they had funded the Internet and more, and wouldn't be innovative without them. Thus, the

same actors that "rode the wave of expensive State investments (…), successfully lobbied government to reduce their taxes" (Mazzucato 2013, 28).

Dispelling myths of the State – Health and Big Pharma

There are other sectors where the State has been captured by myths regarding its role in innovation, such as health. Yet, the State has played a crucial role in health by both creating and innovating new drugs (Mazzucato 2013, 28). The narrative being told is one of an "innovative Big Pharma and meddling government". For example, while being dependent on government-funded R&D, Big Pharma also claims that the government is too restrictive. Still, the health sector receives in many countries "more support than the police force, without providing the jobs or innovation that helps justify such support" (Mazzucato 2013, 28).

Although private pharmaceutical companies have justified their high prices to cover their R&D costs, most of the innovative new drugs come from publicly funded laboratories (Mazzucato 2013, 62). Further, the pharmaceutical sector has been rather unproductive in recent years in producing innovation. Whilst R&D spending by members of the Pharmaceutical Research and Manufacturers of America (PhRMA) had exponentially risen, there had been "corresponding increase in the number of new drugs, commonly known as new molecular entities (NMEs)" (Mazzucato 2013, 63). Of the 1072 drugs approved by the FDA between 1993 and 2004, "only 375 were NMEs" (Mazzucato 2013, 64). The rest were just variations of existing drugs.

Mazzucato uses the U.S. government and its heavy funding of basic science via programs, like the National Institutes of Health (NIH), as an example of the State's role in both funding and creating innovation in biotech (Mazzucato 2013, 66). The investment of key scientific achievements by the State has created the building block for the success of the industry. For example, the NIH spent $365 billion on life sciences research from 1978 to 2004. Since the founding of the first biotech company in 1976, the NIH has used $624 billion (2010) on funding the pharmabiotech sector (Mazzucato 2013, 66). While many researchers acknowledge the immense government support in the science sector, Mazzucato argues that they fail to draw the causal relationship between the successful growth of this industry, its

attractiveness to investors, and "the long-lasting government efforts that develop and sustain the substantial knowledge base found in the US" (Mazzucato 2013, 66).

Innovation-led growth policies – an issue

In the economics of innovation, the focus has been placed on innovation-led growth policies (Mazzucato 2013, 40). These policies focused on the greater investment "in knowledge creation in promoting economic competitiveness". Most importantly, Mazzucato points out that "the causation that occurs in the steps taken between basic science, to large-scale R&D, to applications, and finally to diffusing innovations is not linear" (Mazzucato 2013, 41).

This focus on innovation-led growth policies since the 1980s caused policymakers to focus even more on R&D and patents as predictors of growth and innovation (Mazzucato 2013, 44). However, a large problem with R&D-based innovation policies is the "lack of understanding of the complementary assets that must be in place at the firm level that make it possible for technological innovations to reach the market" (Mazzucato 2013, 46). Literature on the economics of innovation assumes a "direct causal link between R&D and innovation, and between innovation and economic growth." (Mazzucato 2013, 47).

Further, innovation-led policies often include the belief that small firms matter for innovation, growth, and jobs (Mazzucato 2013, 47). Policies will then focus on tax breaks and benefits for small to become more innovative and productive. However, despite the focus on small firms' role in job creation from policymakers, this role of the small firm is a myth (Mazzucato 2013, 48). Mazzucato refers to studies who have found no systematic relationship between firm size and growth. Although small firms by definition will create jobs, "they will also in fact destroy a large number of jobs when they go out of business". (Mazzucato 2013, 47)

Myth of patents in the role of innovation

The myth of patents' role in innovation is similar to the myth that "innovation is about R&D" (Mazzucato 2013, 51). For example, policymakers presume that the pharmaceutical industry is one of the most innovative sectors in the world by looking at the number of patents in the sector. However, policymakers don't realize that a rise in patents does not "reflect a rise in

innovation, but a change in patent laws and a rise in the strategic reasons why patents are being used" (Mazzucato 2013, 51).

An example of patent policy change is the Act, which "encouraged the emergence of the biotechnology industry, as most of the new biotech companies were new spinoffs from university labs receiving heavy State funding" (Mazzucato 2013, 52). Further, there has been a shift in the "use of patents from the development and protection of proprietary technologies, resulting from in-house R&D to cross-licensing in open systems, with the purpose of buying in technology (and the related patents) produced elsewhere". This caused patent numbers of large firms to rise whilst their budget decreased (Mazzucato 2013, 52).

5.4.3. Public values theory and neoliberalism

5.4.3.1. Introduction

Evaluation studies of the Bayh-Dole Act usually focus on the impact of the policy in regard to innovation or academic research culture. Walter D. Valdivia argues that other values, such as distributive equity or political equality, are also important markers for evaluating the outcomes of the Act (2022, 25). Valdivia identifies other outcomes of the Act, such as the affordability of new medical treatments or "bureaucratic regulation of patent-based monopolistic practices" (2011, 26). To broaden the scope of the values considered, Valdivia uses the Public Value Mapping approach for Bayh-Dole Act evaluation to examine the Act through the lens of public values.

5.4.3.2. Public Value Mapping approach

The Public Value Mapping (PVM) approach is a policy examination "through the lenses of the intervening public values. PVM redirects attention in policy analysis from cause-and-effect relations to the articulation-and-realization of public values in the making of policy" (Valdivia 2011, 27). By using the PVM approach, Valdivia evaluates the Act on the basis of two premises, the first which I will discuss in relation to this thesis; neoliberalism.

Valdivia argues that the "systematic changes in both the Bayh-Dole debate and the policy design can be traced to the ascendancy of neoliberalism over U.S. policy-making and to the reforms to the patent system (including the amendments to the Bayh-Dole statute)" (Valdivia 2011, 28).

Factors for change

Neoliberalism had a large impact on social and economic ideas and is the first factor (Valdivia 2011, 28). Although neoliberalism is hard to define, it is generally categorized as a doctrine of political economy that emphasizes private property and free markets. The neoliberal state should then be small but strong enough to enforce property rights and ensure the untroubled operation of markets (Valdivia 2011, 28).

5.4.3.3. Bayh-Dole Act, the surrounding debate and liberalism

The Act debate has changed due to the increasingly liberal attitude of university administrators towards patenting and licensing, and the importance that government officials ascribe to patent protection (Valdivia 2011, 29). For example, university administrators historically thought that patenting should only be done in the public interest and should be affordable and non-exclusive. Today, "university administrators are much more interested in supporting regional (or national) economic growth than in promoting the diffusion of inventions" (Valdivia 2011, 30). The public interest changed due to the new understanding that "growth is driven by industrial innovation" and therefore the administrators "feel the public interest is best served when universities contribute to the creation of new companies".

The ultimate measure of entrepreneurial success "is the firm's market capitalization" (Valdivia 2011, 30). For high-tech startups market capitalization depends on the exclusive rights to key patents. University officers of technology therefore have "fewer qualms about licensing on an exclusive basis than they did thirty years ago". The public interest is then again conflated "with the university's financial need and the financial value of the firms taking licenses" (Valdivia 2011, 30). This constructed change in how the public interest is viewed seems "guided by a doctrinaire view that privileges economic growth over diffusion of innovation – which is a form of economic distribution". Further, they seem to "systematically favor property rights and profit maximizing behavior". Thus, Valdivia argues that these changes are a part of a larger political project called "neoliberalism".

Neoliberal ideas had already started to take hold by the time the Act was enacted in 1980, and the consensus on the welfare state was decreasing (Valdivia 2011, 30). For example, "the most important economic, trade and regulatory policies introduced by every Administration

since Reagan are canonical examples of neoliberal policy-making" (Valdivia 2011, 31). Examples are "deregulation, devolution, the 1995 welfare reform, and NAFTA". Bayh-Dole and its later amendments were a key legislation to perpetuate such policies (Valdivia 2011, 31).

5.4.3.4. Evaluating the Bayh-Dole Act

Assessing policy within the framework of public value means to "identify failures to serve the public interest rather than to positively affirm whether a given policy is furthering the common good" (Valdivia 2011, 38). The failure to consider core public values occurs due to flaws in the "policy-making processes". This could be "ill-designed institutions governing the policy process, or the failures could be procedural" (Valdivia 2011, 38). Public value failure occurs when "private individuals or institutions exercise rights that are the exclusive privilege of the government, such as speaking on behalf of the whole of society or making law and regulations to protect the public interest" (Valdivia 2011, 39). A public value failure also occurs "when researchers conducting those studies have an economic interest in the companies producing the drugs tried" (Valdivia 2011, 39).

The same ensues with regards to the march-in provision, as the government has the statutory authority to enforce march-in rights in the face of monopolistic practices; however, the failure to enforce this provision is thus a public value failure (Valdivia 2011, 39). For example, "three cases were brought to a federal agency petitioning the use of march-in rights" and all were dismissed. Therefore, "the neglect to affirm march-in rights is a public value failure in patent policy, as it would be laxity in enforcing informed consent in the regulation of human subjects in research".

There is also a public value failure when there is a lack of transparency. Transparency is considered "The citizens' ability to exercise oversight over the policy process, from design to implementation" and is termed a "public value of consensus" (Valdivia 2011, 40). Ability for citizens to exercise oversight over policy implementation, especially a policy that affects citizens directly, is crucial. Although the Act "was enacted in a public and transparent fashion, its implementation is not as transparent" (Valdivia 2011, 41). This issue of transparency is later highlighted in Chapter Seven.

5.5. Chapter conclusion

In this chapter I have presented and discussed several arguments used to argue for Bayh-Dole-like legislation. Mainly, I have identified and written out the general causal mechanism for how legislators, politicians and other relevant persons have argued for how patent rights (X) would increase innovation (Y). Innovation is one of the main contributors to economic growth, which happens through the introduction of new FFR, which turns commercialized and thus creates economic growth. As well, I have identified the only theorized CM for how the Act 204 provision (X) would increase domestic manufacturing of FFR (Y).

I have also presented and discussed the general theoretical framework for this thesis and the arguments presented. First, I presented and discussed *What is a patent?* by Hamilton and Till which discuss the dangers of patent policy and its contribution to monopoly-like practices. Second, I presented and discussed general innovation theory. This theory explains the theoretical how and why for the arguments that patents equals innovation, which is crucial to understand the argued CM for how the Act will increase innovation. Third, Mazzucato takes on innovation theory myths, and dispels the myth that the State is slow and un-innovative. The State is highly innovative, and invests in projects that are both harder and larger in scale. Further, the State and Pharma have a "parasitic" relationship, where Pharma is dependent on state funded R&D, yet calls for less regulation. Lastly, Public Value Theory calls for the Act to also be evaluated on public values. Public Value Failure occurs when the state does not do this. Valdivia explains that such instances occur several times with the Act, like with transparency.

6. Method and research design

6.1. Introduction

This chapter explains the analytical and methodological frameworks I used in this thesis. I first discuss the variables used in this study. I present and discuss the uses of qualitative data and why this thesis only uses such data. I discuss the uses of case studies and explain why case study research is the most suitable method for this thesis. I discuss and reiterate what the specific case study method used for this thesis is, which is program (or policy) effects case study. I also present the methods I used to investigate the Act, such as Process Tracing (PT),

which I use to trace potential causal mechanisms between X and Y. Finally, I explain the creation of an original dataset from this investigation.

It is important to note that I do not discuss the process tracing of data in this chapter. This is because the detective-like process tracing of data and how to find it is the second piece of the original research contribution of this thesis. This is the exploration of how to investigate the Act 204 provision, the employment of PT to trace empirical data to the theorized CM and subsequently creating an original dataset from this investigation. Thus, the process in itself and the finding of data is the result of that investigation, and will be detailed in Chapter Seven. To reiterate, the thesis question is:

"*Has the Bayh-Dole Act's 204 "manufactured substantially" provision contributed to the domestic manufacture of federally funded research at the NIH*?".

6.2. Independent and dependent variables

As explained below, I have chosen two variables for this thesis to test the found and theorized causal mechanism (CM) of X on Y. In other words, this thesis is theory-testing and deductive, as opposed to producing results from which one could draw broader conclusions.

My independent variable is the Bayh-Dole Act's 204 "manufactured substantially" provision (X). I chose the "manufactured substantially" provision as my independent variable as this was the provision in the Act that would supposedly maximize the probability of FFR being manufactured in the U.S (96. U.S. Congress, Senate, Committee, University and Small Business Patent Procedures Act, 34). Limiting the scope in this way allows for a more accurate test of the potential causal mechanism described in Chapter Five.

My dependent variable (Y) is the domestic manufacture of the products of FFR. I limit the scope to cover only subject inventions, as these are the only inventions derived from FFR that are subject to the 204 "manufactured substantially" provision. A subject invention as defined by NIH is "any invention of a recipient/consortium participant conceived or first actually reduced to practice in the performance of work under a funding agreement." (NIH n.d.).

To further narrow the field of research, I limit the subject inventions to pharmaceuticals developed in partially or wholly federally funded labs from 1980 to 2007. I did this for two reasons. First, this category of subject inventions is politically relevant today. As mentioned before, exorbitant prices for drugs developed with federal funding led to public debate and a demand for the federal government to use the Act's "march-in" provision (Bettelheim 2023). And second, this category of subject inventions had the most complete and most available data.

6.3. Methodological framework

6.3.1. Qualitative data and its uses

This thesis uses purely qualitative data to theorize and test a potential causal mechanism between the 204 "manufactured substantially" provision (X) and the domestic manufacture of a specific category of federally funded research (Y). Although a mixed method of both quantitative and qualitative data can be useful for case studies, there are several reasons why this thesis uses purely qualitative data (Gerring 2017).

First, this thesis explores unknown territory. No other study has tested the variables used in this thesis. Qualitative data is most appropriate when "not much is known about a subject and when the goal of the researcher is to develop a new concept, uncover a new hypothesis, or shed light on unknown causal mechanisms" (Gerring 2017, 20). Gerring, for example, argues that social science knowledge often begins at the qualitative level and then sometimes proceeds to the quantitative level. This is the hope for this study.

Second, this thesis focuses on a single case and goes in depth. For these kinds of case studies, qualitative data is more likely to be useful (Gerring 2017, 20). Such an investigation, in Gerring's words, "bears close resemblance, methodologically speaking, to a detective's quest to explain a crime, which may be thought of as a single event" (2017, 20). This is also true for this case, as will be explained in detail further in this chapter.

Finally, a major reason for the use of qualitative data in this study is the unavailability of quantitative data on this subject. For example, as shown in chapter four in the AUTM study, there is little to no data on the manufacturing sites for pharmaceuticals created via federally

funded research. This nonexistence of data will also be discussed in further detail Chapter Seven.

6.2.2. A case study – what is it and why is it useful?

This thesis consists of a single case study. As explained below, I selected this approach due to the in-depth investigation of the particular case of the domestic manufacturing location of FFR at the NIH.

Case study "refers to both a method of analysis and a specific research design for conducting empirical inquiry" (Chopard and Przybylski 2021, 1). Some may use case study as a research strategy instead of a method or design. A case study can involve a combination of methodologies, and is defined by Yin (1990) as "an empirical inquiry that investigates a contemporary phenomenon within its real-life context; when the boundaries between phenomenon and context are not clearly evident; and in which multiple sources of evidence are used" (Chopard and Przybylski 2021, 1). Generally, case studies are best suited to answer "how" and "why" questions, "when the investigator has little control over events, and when the focus is on a contemporary phenomenon within some real-life context" (Chopard and Przybylski 2021, 1).

Case study research often relies on multiple sources of evidence which can include direct observation, systematic interviewing and documents. Qualitative data used for case study research is often "richly descriptive because it is grounded in deep and varied sources of information and its "unique strength in its ability to deal with a full variety of evidence" (Chopard and Przybylski 2021, 1). Furthermore, "information is explored and mined in the case study environment for a more thorough examination of the given phenomenon" (Chopard and Przybylski 2021, 1).

With this definition of a case study in mind, this thesis studies a single, specific provision of the Act "in its natural context" and has a "dedicated focus on the links between the phenomena and its contextual interrelationships, and what the links can tell us about either the uniqueness of the case or its generalizability to comparable relationships" (Chopard and Przybylski 2021, 1). It focuses on the special policy of the 204 "manufactured substantially" provision, and the unique case of the manufacturing site of federally funded pharmaceuticals

at the federal agency NIH. From this, I draw some initial conclusions about how well section 204 has delivered on its intended purpose and outline data gaps that could be filled through further research.

This thesis uses multiple sources of data such as documents, internet websites, patent numbers and more. The availability of data and its uses, and which data are used, are key themes in this thesis that I discuss in this and other chapters.

6.2.3. Program effects case study – what is it and how does it relate to this thesis?

This thesis is also a program effects case study. Researchers use program effects case studies to "determine the effects or impacts of a program and illustrate reasons for successes and failures" (Chopard and Przybylski 2021, 2). In other words, program effects case studies answer "how" and "why" questions about program or policy effects. This thesis attempts to answer whether the 204 "manufactured substantially" provision has had an effect, and if so, how (the causal mechanism).

Program effects cases studies "attempt to unpack what's inside the "black box" of a program and explain the mechanisms or actions through which program effects or impacts take place" (Chopard and Przybylski 2021, 2). The "program effects case study is a form of explanatory case studies" (USAID 2013, 3). Although there are different types of explanatory case studies, this type focuses specifically on program or policy effects.

Program effects case study, or ex-post evaluation, is the classic method of evaluating goal attainment and the effects of policies and measures, once they have been completed" (Wollman 2007, 394). Ex-post policy evaluation has "often been identified with program evaluation".

Policy evaluation typically has two tasks: the first is producing an assessment "about the degree to which the intended policy goals have achieved ("goal attainment")". The conceptual difficulty that may arise from goal attainment revolves around the conceptualizing of the appropriate, if possible measurable, indicators". In addition to identifying the "intended" consequences, "the assessment of the effects of policies and programs came to

pertain also to the non-intended consequences" (Wollman 2007, 394). The second task when evaluating policies and programs is to answer the "causal question as to whether the observed effects and changes have really (causally) related to the policy or program in question". Determining whether the policy or program produced observed effects requires methodological tools and skills that can solve the "causal puzzle" (Wollman 2007, 394).

6.2.4. Process tracing – what it is, and how one uses it to trace causal mechanisms

This thesis both identifies the effects of section 204's "manufactured substantially" provision and attempts "to unpack what's inside the "black box" … and explain the mechanisms or actions through which program effects or impacts take place" (Chopard and Przybylski 2021, 2). To explain the causal mechanism (CM) of section 204, I use the method of Process Tracing (PT). PT involves a kind of detective work, in this case tracing the theorized CM and testing whether it exists in reality. I further test whether the theorized CM has an outcome or an effect on Y. Finally, I evaluate the certainty of the CM and the validity of the research results.

PT is at its core a "distinct case-study methodology that involves tracing CMs that link causes (X) with their effects (i.e., outcomes) (Y)" (Beach 2016, 463). There are two reasons to trace the mechanisms by which a cause produces an outcome. First, tracing CMs allows us to "make stronger evidence-based inferences about causal relationships when we have within-case evidence of each step of the causal process (or absence thereof) in between a cause and outcome" and especially, the "activities that provide causal links in the process". Second, "tracing mechanisms gives us a better understanding of how cause produces an outcome".

Thus, process tracing can help to test or to build theories of CMs (Beach 2016, 463). In this thesis I test the CM theorized by senator Bayh, as explained earlier. I also trace the process of this theorized CM to see if, in reality, this cause could produce the desired outcomes.

Beach argues that in order to "reap the analytical benefits of PT in terms of better theories and stronger evidence-based claims about causal process" one needs to "unpack mechanisms into their component parts in enough detail to enable us to know exactly what we are

attempting to trace" (2016, 464). It is especially important to focus on the "activities that provide the causal links between each part of the causal mechanism".

Breaking a CM into its component parts requires understanding what those parts might be. According to Beach, "the simplest understanding of mechanisms found in the literature is to see them merely as a series of events, or a narrative story leading to an outcome" (2016, 464). However, although describing "a series of events can provide a plausible descriptive narrative about what happened, they do not shed light on why things happened in the case". As such, causal explanation "involves more than just tracing temporal sequences", and the causal mechanism remains "black-boxed" (Beach 2016, 464).

Beach maintains that CMs should be taken seriously as a "causal process by treating them as theoretical systems linking causes and outcomes" (2016, 465). In this context, "a causal mechanism is defined as a theory of a system of interlocking parts that transmits causal forces between a cause (or a set of causes) and an outcome". As such, "a theorized causal mechanism describes each part of the mechanism whereby causal forces are transferred from cause to outcome".

The parts of a CM can be defined as "entities that engage in activities that transmit causal forces from cause to outcome". Entities can then be understood as factors such as actors or structures "engaging in activities, where the activities are the producers of change or what transmits causal forces through a mechanism" (Beach 2016, 465). It is the activities in which entities engage in that moves the mechanism "from an initial causal condition through different parts to an outcome". This explanation of CMs and how they work differs from a "theory as a causal graph in which the activities are not described, but merely depicted as causal arrows linking one entity to the next" (Beach 2016, 465). Therefore, a CM consists of both entities and the activities in which they participate.

6.2.4.1 Theorizing causal mechanisms

When theorizing parts of a CM it is important that there is logic behind the sequence of the parts and that there are no large "logical holes in the causal story linking X and Y together" (Beach 2016, 465). The mechanism is represented as such: X (Bayh-Dole Act 204 provision) [A B C] Y (domestic manufacture of federally funded research/subject inventions). The

logical continuity lies in the arrows between events and activities, as well as the "transferal of causal forces from one part of a mechanism to the next" (Beach 2016, 465).

Beach contends that one is often not able to get much more than what Machamer calls a "mechanism sketch" (Beach 2016, 465). Even so, some information about a process, even a crude depiction, is better than no information (Beach 2016, 465). But best practice when conceptualizing a causal mechanism is to clearly identify each part of the mechanism and how they are linked to each other through activities. Doing so results in "better causal theories, and in actual empirical tracing of causal processes in cases, enabling stronger inferences to be made as a result" (Beach 2016, 465). This enables us to closely inspect the causal logic for each link in the causal process. In addition, "by actually tracing causal processes in detail in an empirical case study, evidence is provided suggesting either that the mechanism was present, the mechanism should be revised because it did not work as theorized, or there is no causal link". No causal link suggests that there is no causal relationship (Beach 2016, 465).

In process tracing case studies the researcher makes inferences by determining the match between the evidence found and the predicted evidence for each part of the mechanism (Beach 2016, 468). This can take the form of empirics-first research, where the researcher first collects empirical material and then evaluates the causal process there might be evidence of. Another approach is theory-first research, where the researcher theorizes and develops expected evidence for each part of the theorized mechanism and then evaluates whether the empirical evidence lines up with this (Beach 2016, 468). This thesis is empirics-first research.

Beach distinguishes between four types of evidence that can prove the existence of each part of a causal mechanism. The first is pattern evidence, or "statistical patterns in the empirical record" (Beach 2016, 469). The second is evidence for a temporal or spatial sequence of events from which the researcher can infer causation (Beach 2016, 469). For example, when testing a theory about rational decision-making, relevant evidence might be whether decision-makers first collected all relevant information, evaluated it, and then took the decision that they believed best solved the policy problem they faced. If instead decision makers took a decision before they collected information, the researcher would have less confidence that rational decision-making applied. The third type, trace evidence, "refers to material where its mere existence provides proof". And finally, the fourth category is evidence where the

content matters, which can be in the form of documents like legislative proposals (Beach 2016, 469).

6.2.6. The CM (M) between X (204 "manufactured substantially") and Y (domestic manufacturing)

As discussed in the theory chapter, there are several potential CMs theorized in the hearings prior to the enactment of the Act on how the Act would have an effect on the intended goals. First, the generally used CM for how Act-like legislation would work is by: giving the patent (X) rights of federally funded research to the organization or company that did the research would create an incentive for them and other organizations or companies to participate in federally funded research and design. This would in turn fuel innovation through the creation of new research and thus products, which would increase the rate of commercialization of federally funded research which is a positive impact/effect on innovation (Y).

6.2.6.1. The CM of the 204 provision and domestic manufacturing

The identified and argued CM between the Bayh-Dole Act and domestic manufacture of federally funded research is clearly laid out by Senator Bayh. To repeat: By having section 204 (X) provide that persons receiving exclusive licenses must agree to manufacture any products embodying the invention substantially in the United States (Y). By having products manufactured in the U.S., will then subsequently "benefit American workers". As discussed earlier, this is a simple CM. Not only does it not explain both events and activities that are initiated by actors, but it is also vague.

6.2.6.2. Completing the identified CM of X on Y

When digging through the hearings on the Act prior to 1980 as well as similar legislations, there were many theorized CMs of how each part of the Act would work, put forward by both legislators and witnesses testifying before Congress. Despite many arguments of how the legislation would work on the Act's intended effect such as patent policy and use of exclusive licenses, there was only one finding of a potential CM between X and Y found in the hearings and governmental historical records. Senator Bayh's analysis of the 204 "manufactured provision" and how it was designed to work is the only potential CM found in the historical material that actually theorizes the link between X and Y. I theorize this simple

CM further to a more complete and accurate CM, and the visualization of the CM can be found in Figure 1 and Figure 2.

The applicable federal Agency, such as the NIH, approves funding for research, a subject invention, performed by an actor. The actor signs an agreement with recipient organization agreeing to:

> (1) disclose promptly in writing to personnel identified as responsible for the administration of patent matters each Subject Invention made under NIH funding; (2) assign to the Recipient the entire right, title and interest in and to each Subject Invention made under the funding agreement; (3) execute all papers necessary to file patent applications on Subject Inventions; and, (4) establish the government's right in the Subject Inventions (NIH 2022).

The actor must then disclose the subject invention to NIH. Within two years of disclosing the subject invention, the actor must decide to elect title to the subject invention. If the actor decides to elect title to a subject invention, the actor must file an Initial Patent Application. Within the Initial Patent Application, there must be a confirmatory license declaring the Government’s right to the invention throughout the world. The actor must then also clearly state in any documents related to the patent “This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention.". That is how one knows that the patent is a subject invention created with federal funding.

The actor’s filed Patent Application is for the sake of this CM approved. When the Patent Application is approved, the actor agrees to terms laid out by the Federal Agency when the actor wants to apply for an exclusive license of the federally funded research, a patent. When receiving an exclusive license from the Federal Agency (the NIH), the actor agrees to terms and provisions laid out by the Act. Included in these terms and provisions is the 204 “manufactured substantially” provision, which states that all products derived from federal funded research must be substantially manufactured in the U.S. The 204 “manufactured substantially” provision is also applicable if the actor decides to third-party out the patent rights, which can only happen if the third-party also agrees to manufacture the subject invention in the U.S.

A waiver can be requested and sent into the NIH if the actor or third-party has discovered that they cannot manufacture substantially in the U.S. To do so, the actor or third-party must detail explicitly in the waiver request exactly why they cannot manufacture substantially in the U.S. In the case where the actor can manufacture the subject invention in the U.S, the actor then turns to the activity of getting the now producible product manufactured in the U.S. The actor finds a domestic manufacturer for the now producible product, and thus domestically manufactures federally funded research. In the event that the actor has found they cannot manufacture substantially in the U.S, the actor then requests a waiver from the NIH. If the waiver request is approved by the NIH, the actor then finds a manufacturer outside of the U.S. and thus does not manufacture federally funded research domestically.

Figure 6.2.6. (1) Causal mechanism for how X is to have a positive effect on Y.

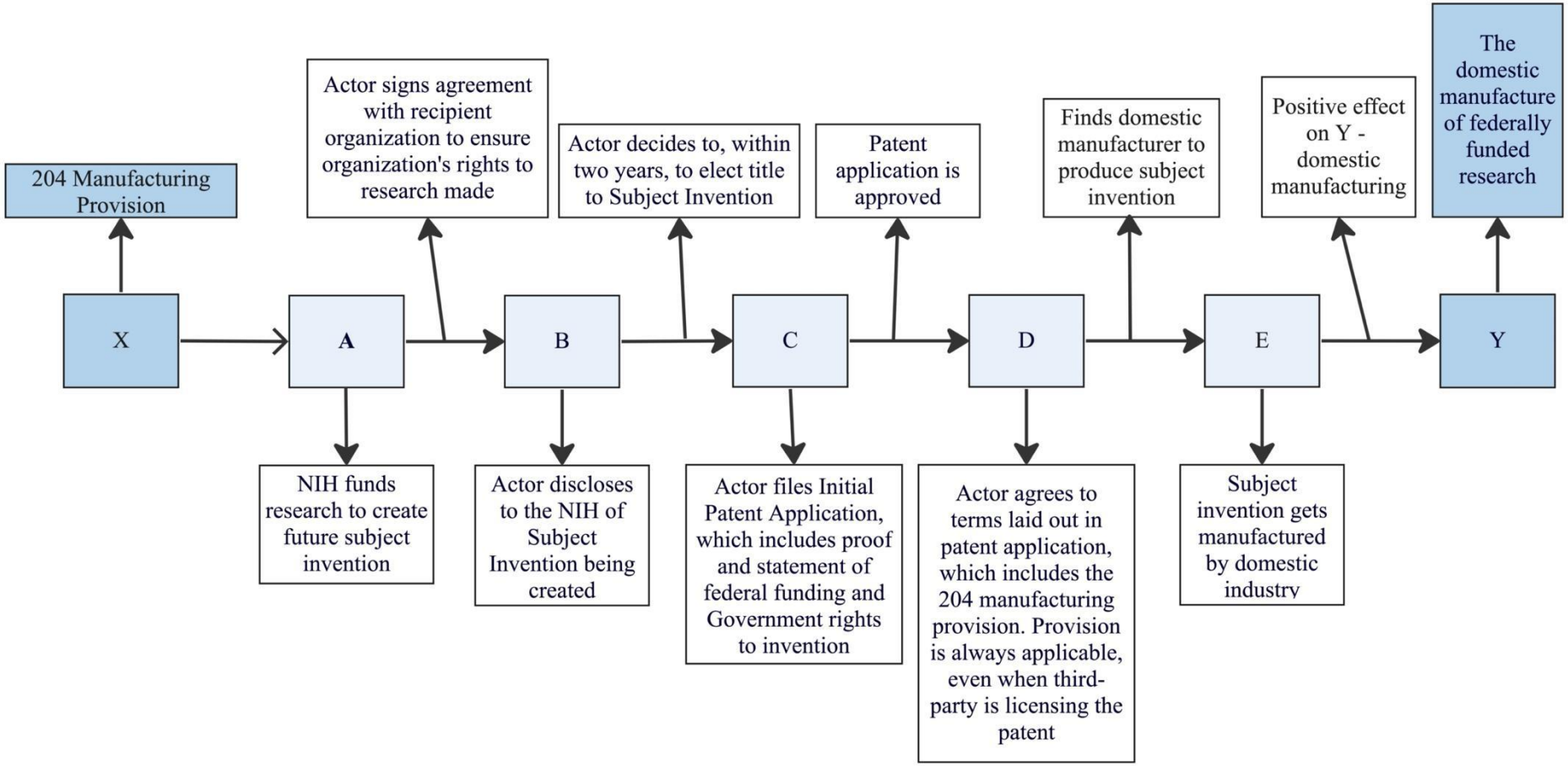
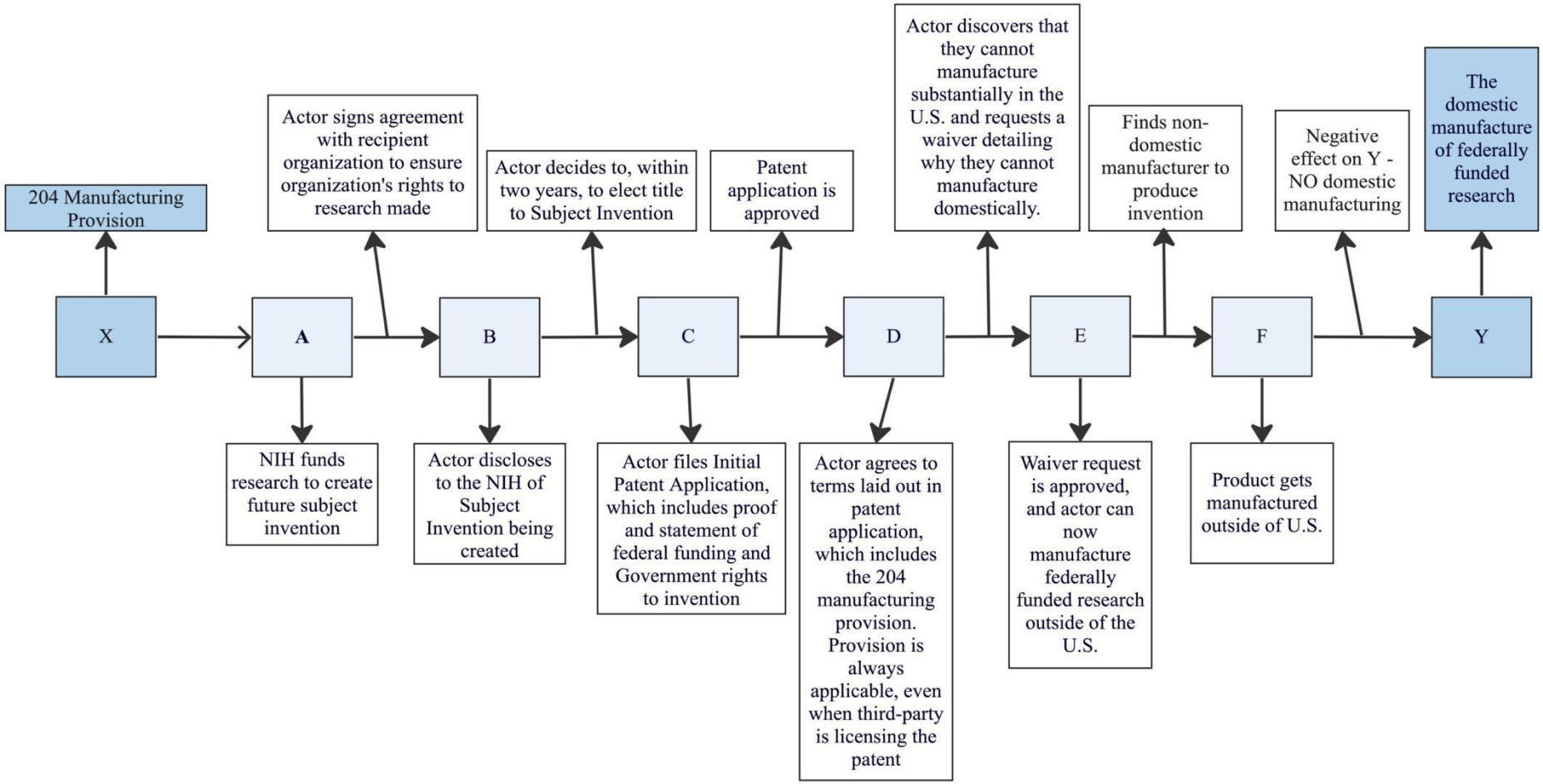


Figure 6.2.6. (2) Causal mechanism for how X is to have a negative effect on Y.



7. The investigation: Process Tracing for data and the collection, organization and creation of the original dataset1

7.1. The thesis

7.1.1. Why section 204 of the Act deserves a closer look

Though policy makers may overlook the Act, it directly impacts several important political issues. Not only does the Act affect who receives taxpayer funds, but also it also influences what kind of research receives funding and who benefits from the research that the funding supports. There are large sums of money involved: The U.S. government spends $160 billion on R&D annually, and the NIH spent $31 billion on R&D funding in 2022 alone (Kota and Mahoney 2022) (NIH IMPACT 2022).

The Act affects how research is commercialized, who gets to commercialize that research, and who benefits from that commercialization. Private actors, including research universities, small businesses, and large corporations get to choose how to introduce federally-funded research to market. These can be life or death decisions as federally funded research has produced lifesaving or life-altering drugs. For example, three of the drugs I will present in this chapter treat HIV. More recently, federal funding drove the research behind the COVID vaccines, with Moderna, Janssen Pharmaceuticals, Sanofi/GSK, and Merck/IAVI (Congressional Research Service 2021).

The Act also affects technology development and advancement in critical areas for society outside of pharmaceuticals. For example, the Act is highly relevant to the Department of Energy, which funds the development of key technologies to reduce greenhouse gas emissions and address climate change. As mentioned above, the DOE has strengthened its implementation of section 204 by issuing a series of Determinations of Exceptional Circumstance (DECs) that strengthen and enforce the domestic manufacturing requirement. The meaning of the DECs will be discussed in detail in this chapter.

[1] Data collected to create the original dataset is available upon request to Thea Tufte at the Department.

The manufacturing chain of produced goods is not only relevant for pharmaceuticals, but all other sectors that benefit from federally funded research. As mentioned, domestic manufacturing is deeply important to the DOE and development of energy technologies.

7.1.2. Why this thesis contributes original research to study of the Act

The goal and objective of the Act is to promote the commercialization and public availability of inventions made in the United States by United States industry and labor. Manufacturing is a crucial step to realize this goal. However, there has been virtually no research into whether the Act in fact has promoted domestic manufacturing.

My thesis attempts to close some of the research gap surrounding section 204 of the Act. By asking "*Has the Bayh-Dole Act contributed to the domestic manufacture of federally funded research*?", I seek to answer if the Bayh-Dole Act has in fact achieved its goal of manufacturing inventions made with federal funding in the United States by United States industry and labor.

This thesis also explores broader and less studied questions about whether the Act is still fit for purpose. Asking whether the Act has functioned as intended on a key issue - manufacturing - opens up a discussion about whether the Act as a whole has delivered as promised. As explained above, a set of assumptions and ideologies about the roles of the state and the private sector drove passage of the Act. Does the implementation of the Act show that those assumptions were correct? Has the Act delivered the public goods that its supporters envisioned? Who has benefitted? How are the goods that stem from this Act distributed? And what future legislation could be passed to address any deficiencies of the Act?

Finally, this thesis attempts to fill another, quite fundamental research gap: The absence of data about the effects of section 204 on domestic manufacturing. As I explored the topic, I discovered that there was no readily available data on this topic and that I would have to reconstruct this data from other available information. I had to engage in detective work.

This chapter tells the story of how I developed the original dataset for this thesis. It explains the steps I took to identify relevant data and process trace the theorized causal mechanism (CM). I started by identifying which categories of data were relevant for the

thesis question. I then considered what sources of information could provide this data. These ranged from statistics on patents at the NIH after the passage of the Act to section 204 waivers, official government documents relating to the Act, and information found online about pharmaceutical products and their countries of manufacture, patent information, university records, etc.

Thus, this chapter highlights what I consider to be an independent contribution of my research: The exploration and identification of where relevant data exists, the collection of these data, and the analysis of the data. In finding empirical evidence for the CM, I traced, found, collected, organized and analyzed the data needed to answer the thesis question. This is an original data set and perhaps the process I describe will help other researchers to identify more data on this issue.

7.2. The manufactured substantially waiver system

To commercialize and patent federally funded research, the grantee of federal funds agrees to the terms laid out by the Act and the relevant federal agency. These terms include the "manufactured substantially" provision, which establishes a preference for U.S manufacturing for "subject inventions" that result from FFR. Unless the grantee applies for a waiver, the Act requires grantees to "manufacture substantially" the product in the U.S.

In theory, the substantially manufactured provision should increase domestic manufacturing as there would be more domestic manufacturing of inventions developed with FFR. This is the original simple CM of the Act, as described in Bayh's analysis of the Act (96. U.S. Congress, Senate, Committee, University and Small Business Patent Procedures Act, 34). The provision would maximize the probability of the domestic manufacture of federally funded research by ensuring that every entity and person receiving an exclusive license agreed to the terms of section 204's "manufactured substantially" provision.

Positive outcomes of this theorized CM would require several steps: The federally funded research resulted in an invention that was viable, patentable and producible; the grantee found a domestic manufacturer for the patented product; and the domestic manufacturer produced the patented product at a commercial scale. Negative outcomes of this causal mechanism would occur if FFR did not result in viable, patentable, and producible

inventions; or if all grantees applied for and received waivers that allowed the grantees to manufacture the product outside of the U.S.

As explained earlier, when theorizing this CM it is crucial to distinguish between regular federally funded inventions and "subject inventions". Not all inventions created through FFR are "subject inventions", but only "subject inventions" are covered by the 204 "manufactured substantially" provision. Therefore, statistics, numbers or patent information that differentiate between regular inventions and subject inventions are essential to measuring whether the "manufactured substantially" provision works.

7.2.1 The waiver system, its potential for empirical causality, and research strategies

One way to demonstrate empirical correlation for the CM would be through the waiver system for section 204 "manufactured substantially" provision. Here, a causal mechanism could be: If the inventor of a subject invention created with federal funding applies for and receives a section 204 waiver, that indicates that the subject invention will not be manufactured substantially in the U.S.

By getting data on how subject inventions there were under the Act, and how many of those applied for and received a section 204 waiver, it would be possible to show what proportion of the total number of subject inventions under the Act were manufactured in the US. These are the events found in Figure 6.2.6. (2) and events E and F. This would be the ideal method to test the causal mechanism between X and Y and was my research "Plan A.". This method would also allow for a concrete evaluation of either the negative or positive effects of section 204's "manufactured substantially" provision on the domestic manufacture of federally funded research.

Thus, getting waiver data was my research "plan A." However, if this data was not available, my plan B was to find pharmaceutical products that were created with federal funding, research them and the company that owned the patent or the product, and find the manufacturing site for that product. Plan B would essentially involve building my own dataset with publicly available information. This is what I ended up doing, with modifications.

7.2.2. Investigating plan A

To investigate plan A, the waivers, I spent a significant amount of time doing research online to see if there were any statistics on the waiver system. I explored waiver data at the NIH and other federal agencies. I found that "all Bayh-Dole U.S. manufacturing waivers for the NIH are currently administered by the Division of Extramural Inventions & Technology Resources (DEITR) in the NIH Office of Extramural Research (Struver 2016). I emailed and called this office as well as NIH's central office, asking for assistance in finding waiver information. I also emailed and called the National Science Foundation, which deals with research grants to universities, asking for assistance in finding information. As of the time of publication, I have not heard back from either federal agency.

Next, I found that the NIH Office of Technology Transfer (OTT) keeps statistics on the granting of waivers between 2011 and 2015 on their official website. Using an internet archive program, I was also able to find NIH statistics from 2009 to 2011. This was exactly what I needed in order for plan A to work. For each year, the statistics told me how many inventions were patented and how many received a waiver. For example, according to NGO Knowledge Ecology International, which made a FOIA request to NIH, the NIH approved almost all waiver applications between 2014 and 2015 (Struver 2016).

However, although NIH statistics showed how many applicants applied for and received waivers, they did not differentiate between regular inventions and subject inventions. Without that crucial distinction, it would be impossible to show how many subject inventions there actually were, how many of them received waivers from the NIH, and therefore whether the "manufactured substantially" provision was effective. And with no response from NIH or NSF, and no information on where I could access data that distinguished between the two categories of inventions - all inventions and subject inventions, this line of research was a dead end.

7.3. Universities route – and more dead ends

Whilst doing the research mentioned above, I emailed experts on the topic of technology transfer and/or the Act. First, I emailed and corresponded with Gerald Barnett (PhD), who has extensive knowledge on the subject of the Act and technology transfer. Mr. Barnett runs

the Research Enterprise, which is an Internet site dedicated to research and debate on the Bayh-Dole Act. He provided the help I needed to move forward in my search for data. I also emailed and spoke to James Love, the director of Knowledge Ecology International (KEI), which is an NGO that has looked into the manufacturing aspect of the Act. Mr. Love steered me to the Food and Drug Administration Orange Book, which is a government database of FDA approved drugs, and the NIH technology transfer statistics.

Although bias might occur when receiving information from experts, both experts steered me in the direction of Government driven databases and information, and peer-reviewed articles.

Speaking to experts on the subject, finding the technology transfer statistics, and several more dead ends led me to my first real lead. I thought that since universities are a key part of the FFR ecosystem, finding inventions via universities could work. I would first have to find sites of research production, such as public universities, identify all of the inventions claimed by those universities in a given time period and derived from FFR, and see which of their patentable inventions had reached commercialization and use.

However, this method too proved to be a dead end. First, it proved to be very difficult to get this information from universities. Universities generally do not publish or report on inventions produced from FFR. Getting this information would require digging through annual reports from technology licensing offices, offices of research, and other bodies.

I then tried accessing private intellectual property databases and patent databases. However, these programs and companies seem to be geared towards private sector organizations rather than researchers. I concluded that this lead would be time-consuming with a low potential for the information I needed.

7.4. The Department of Energy and the Determination of Exceptional Circumstances

Around this time, I learned of the Department of Energy's (DOE) announcement of a new Determination of Exceptional Circumstances (DEC) relating to the application of section 204.

Like the NIH, DOE funds a lot of research with a budget that spans billions of dollars, significantly more than the NIH (Office of Chief Financial Officer 2021). The Act plays an important role in DOE's system of research funding: "Rights to inventions that Contractors conceive or first actually reduce to practice in performance of work under a funding agreement ("subject inventions") are governed by Bayh- Dole and the federal regulations that implement Bayh-Dole" (Office of General Counsel n.d.).

Under section 401.3 of the Act, a federal agency can in exceptional circumstances keep title to the subject invention "when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of Chapter 18 of Title 35 of the United States Code". DOE interprets this standard clause to mean that "federal agencies may determine that "exceptional circumstances" exist such that a modification in the patent rights disposition provided under the Act would better promote its objectives" (Office of General Counsel 2014).

The DOE has issued ten DECs since the Act passed in 1980. As shown in Table 1, out of the ten DECs four are related to domestic manufacturing of federally funded inventions. The DOE issued three of those four DECs specifically to promote or improve the domestic manufacturing of federally funded inventions. DOE issued the first DEC that imposed the "manufactured substantially" requirement in 1985, only five years after the enactment of the Act (Office of General Counsel n.d.). DOE issued the second DEC in 2013 and it is the first DEC that proposes the use of a plan to better enforce the requirement of domestic manufacture of federally funded inventions (Office of General Counsel n.d.). DOE issued the third DEC, titled "Determination of Exceptional Circumstances under Bayh-Dole Act for quantum information science technologies", in 2020. It also introduces a requirement of domestic manufacturing (Office of General Counsel n.d.).

Table 7.4. Summary of DECs and year issued. Source: Office of General Counsel n.d.

DOE DEC Year issued	Summary of DECs
1985	First mention of manufacturing in issuing of DECs (Department of Energy 1985).
2013	Found that exceptional circumstances "existed for disposition of patent rights arising under research, development, demonstration, and market transformation projects involving energy efficiency, renewable energy, and advanced energy technologies …to better promote U.S. manufacturing". Further, "to better meet the objectives of Bayh-Dole, which include the goal of promoting commercialization of inventions by United States industry and labor, DOE proposes the use of U.S. Manufacturing Plans in funding agreements" (Department of Energy 2013).
2020	Introduces a domestic manufacturing requirement: "Exceptional circumstances exist to establish a U.S. Competitiveness requirement for the disposition of patent rights arising under research, development, demonstration, and market transformation projects involving quantum information science (QIS) technologies and applications, as described herein, to better promote U.S. Competitiveness and protect critical national interests in U.S. leadership in QIS.". Further, the "U.S. Competitiveness requirement is narrowly tailored to provide stronger support for U.S. national security and economic interests, such as U.S. manufacturing, while maintaining the rights of small businesses and non-profit organizations to commercialize their federally funded inventions" (Department Of Energy 2020).
2021	"In connection with the 100-day review of critical supply chains as directed under E.O. 14017, America's Supply Chains, the Science and Energy Determination of Exceptional Circumstances (S&E DEC) was announced as part of a series of new policy actions to support U.S. job creation and bolster the domestic manufacturing supply chain. The S&E DEC expands on DOE's many years of experience in strengthening U.S. manufacturing requirements in DOE-funded grants, cooperative agreements, and research and development contracts by extending the enhancement of U.S. manufacturing requirements to most of the DOE Programs. The S&E DEC ensures that all innovations—including those relating to advanced batteries—developed with taxpayer dollars through DOE Science and Energy Programs are substantially manufactured in the U.S. Specifically, the S&E DEC authorizes inclusion of the U.S. Competitiveness provision, which requires substantial U.S. manufacture of products embodying DOE-funded subject inventions, in agreements funded by DOE Science and Energy Programs" (Department of Energy 2021).

DOE's DECs show a progressive strengthening of domestic manufacturing requirements. Previous U.S manufacturing requirements were either section 204 of the Act, the baseline standard for federal agencies, or the U.S Competitiveness provision. The latter was a domestic manufacturing requirement that applied to cooperative research and development agreements and "entities obtaining patent waivers from DOE under DOE's statutory patent waiver authority" (Department of Energy 2021). For example, the DEC that DOE issued in 2020 outlined a U.S Competitiveness requirement for FFR in quantum information technologies.

In particular, the 2021 DOE DEC is a step change. It expands the U.S Competitiveness requirement to cover all inventions that DOE funds. This means that all new funding agreements signed after DOE issued the DEC will include the U.S Competitiveness provision, allowing the agency to control, regulate and oversee the manufacture of federally funded inventions in a much broader way than NIH, for example, has done.
DOE's arguments in support of the 2021 DEC signal this step change and a more intentional approach to promoting domestic supply chains for inventions from FFR. Echoing certain language from Congressional hearings on the Act, DOE issue the DEC to call for "increased domestic manufacturing to promote commercialization of DOE Science and Energy Technologized by U.S industry and labor", but also to "provide stronger support for U.S national security and economic interest" (Department of Energy 2021).

DOE's DECs were a helpful data point in finding answers to the thesis question. They show that the thesis topic is highly relevant, because an agency that is responsible for significant FFR has directly addressed the issue through administrative action. They also indicate a markedly different approach to section 204 than taken by NIH. This in turn opens up questions about what latitude federal agencies have to interpret the Act, and why different agencies have taken different paths. .

7.5. The waivers – again

Whilst still investigating plan A, the waivers, I learned of the FDA Orange Book, which lists related patent and exclusivity information of FDA-approved drugs. With the Orange Book I would be able to tell when a patent was first approved, if the drug was still in circulation, and other useful information. However, I found that the Orange Book is missing a lot of the patent information that it should contain.

I also found The Drug Patent Book, an NGO that keeps track of all the patents related to ten of the most known drugs (in the US). For example, the drugs Revlimid and Humira were both created in federally funded labs and are at the heart of several drug price controversies (Higgis-Dunn 2021) (Rowland 2020).

Around this time, I decided that since my efforts to get help from the NIH or NSF were not working and that I would need to file a Freedom of Information Act request to get the information I needed. Unfortunately, a FOIA request takes months. The likelihood of my request being seen, fulfilled and sent back to me within the time that the data collection process needed to be done was very slim. I sent the FOIA request anyway, in hopes that I might hear back in time.

7.6. The turning point – "The Role of the Public-Sector Research in the Discovery of Drugs and Vaccines"

Throughout the research process of looking for accurate, viable data I found that there was little gathering of and reporting on the macroeconomic outcomes of the Act, apart from university patenting and licensing. Furthermore, I found that there was very little information or data available on the "manufactured substantially" provision, without going through a FOIA request. So far, I had gotten nowhere with emails and calls to the NSF and NIH, as well as other searches I had done. And without the right data, it would not be possible to answer the research question.

The turning point was finding the article "*The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*" written by Ashley Stevens et al. (2011). The article discusses the more direct role the public sector has in R&D now, compared to the beginning of biotechnology. The authors found and identified new drugs and vaccines approved by the Food and Drug Administration that public-sector research institutions discovered between 1962 and 2007. The article was published in the peer-reviewed journal *The New England Journal of Medicine*, and is therefore empirically verified data that is appropriate for use in this study.

In an appendix to the article, the authors list all the drugs and vaccines created and discovered in public-sector research institutions (PSRI), with 90 drugs in total. This appendix contained the precise type of data I needed to answer the research question: "*Has the Bayh-Dole Act of 1980 and its 204 "substantially manufactured" provision contributed to the domestic manufacture of federally funded inventions at the NIH?*". This was crucial, as it set the stage for collecting the remaining data. This list of 90 drugs created between 1982 and 2007 is the

basis of the original dataset that I created on the domestic manufacture of FF pharmaceuticals.

7.7. Start of creating original dataset

So far, the research process involved lots of investigation and reaching out to others to find accurate, viable data that could empirically validate each of the causal events. The process eventually led me to do a modified version of plan B, creating my own dataset. This was the only way to answer the research question accurately, with a very specific type of data that did not exist in an organized form elsewhere. By using the existing list of 90 approved FDA drugs created in PSRIs, I would be able to determine with the FDA Orange Book which drugs were created after the enactment of the Act (1980). If they were, then they would be subject to the law, and to section 204.

First, to determine whether this method would work I looked through the list and found several drugs that were also listed in the Drug Patent Book. The drugs I first searched for from the Drug Patent Book were well-known, like Revlimid and Humira. Whilst doing this research, I learned that I could search for the patent in Patent Public Search (USPTO) if I could find the patent number for each invention. Searching the number in USPTO would allow me to find the original patent, which would tell me if the patent was a subject invention or not. If it was a subject invention, a "government interest" notice (GI) would then be visible in the original patent, and that would give me proof that the invention was a subject invention. To ensure that the patent I found in USPTO was indeed the patent for the correct drug, I checked the drug information to ensure that it matched the information in the appendix. This included the original assignee of grant (which university), which company commercialized the drug, when it was created and the active ingredient.

This led me to develop the following research process: Pick a drug from the list, look the drug up on Google and try to find an original patent number for that drug, look the patent number up in USPTO and see if it is a subject invention or not. If the drug is a subject invention, search on the web for the manufacturing location of said drug and/or the manufacturing location for the company that manufactures and sells the drug.

After researching the drugs in the Drug Patent Book that matched those listed in the appendix, I then decided to systematically go through the entire list of drugs starting at the top of the appendix and try to find each drug's individual and original patent number. This process would allow me to get empirical validation of each causal event, such as the invention being a subject invention.

This process was time consuming and only partially effective. First, it was only possible to find the original patent numbers for some of the more popular drugs. There were usually one or more articles online discussing these drugs and their patents, and these articles often included the drug's patent number. When I was able to find the drug's patent number, I could look it up on USPTO. I discovered that none of the drugs listed in the Drug Patent Book were subject inventions. But second, for the lesser known or used pharmaceuticals, finding the original patent number on Google was nearly impossible. This raised issues of transparency about the implementation of the Act, because information was not readily available online or elsewhere.

7.7. Patent search program and creating the original dataset

The creation of the original dataset progressed when I started to use the patent information website Drug Patent Watch, which is a system for corporate users to find information on patents. In this case, it was the only program I found that listed the patent information I needed in order to confirm whether each drug was a subject invention.

7.7.1. Process of identifying which drugs were subject inventions

After finding the program, I started at the top of the list of 90 drugs created in a PSRI, such as the drug Lyrica. I searched for Lyrica in the FDA Orange Book, which stated that the drug was not discontinued and approved after 1982 (the Act did not go into effect until 1981) (KEI Online n.d.). Since much of the patent information that should be available in the Orange Book is not in fact available, I then searched for Lyrica on drugpatentwatch.com. Search results on drugpatentwatch.com varied, as some searches had the current patent number and others did not. I then sifted through the expired patents where the patent number was almost always available, to find the original patent number.

I then looked up all the patent numbers on USPTO, to find the original patent where the assignee of the grant (a university or a research organization) matched the university or organization stated in the appendix. That way I was able to cross-reference that the patent was indeed the original and that all the information matched between the patent and the appendix. I then looked for a GI notice in each patent that I sifted through on USPTO. Any patent without a notice would not be a subject invention in this dataset.

For each patent with a GI notice, I created a spreadsheet with key information. That included the original drug name/ingredient, the commercialized drug name, assignee of the original grant to create the drug, when the drug was first patented, who is currently marketing the drug, if it is manufactured in the U.S, what is the date of the information about where the drug is manufactured, the source of information, a screenshot of the source, if it is a subject invention, and the proof of subject invention which is either an URL or the patent number with the GI notice. I also created a map for each drug with screenshots of the information I found online. This is to ensure that all necessary information is included, verifiable, and could be reproduced even if the information disappeared from the web. After completing my search, I found that ten of the ninety drugs were subject inventions.

After determining which of these 90 drugs were subject inventions, I investigated each of these ten drugs and the companies marketing them to find the manufacturing location for the drug. Relevant information or data included news articles, stakeholder letters, 10K forms that the companies filed with the Securities and Exchange Commission, and so forth. In the final dataset, I divided information on manufacturing into three groups: Website information, which could include company websites, drug information websites, etc; 10K filings; and news articles.

7.7.1 Lyrica - Viatris

The first subject invention, Lyrica, is sold by Viatris (formerly Upjohn). It is a widely used drug that treats epilepsy. To determine whether it was manufactured in the US, I searched online for information on Viatris' locations, Upjohn's former locations, and specific information on Lyrica. According to a news article from 2018, Lyrica is wholly manufactured in Puerto Rico. According to Viatris' 10K filing, the company has an agreement with the Puerto Rican government that exempts Viatris from income, property and municipal taxes

until 2029. For Lyrica, the evidence that it is manufactured in the US is in the form of a news article and the company's SEC filing.

7.7.2. Xalatan - Viatris

Xalatan, which is used to treat the symptoms of open-angle glaucoma or ocular hypertension, is also sold by Viatris. Although available evidence indicates that Viatris manufactures most of their drugs for the US market in Puerto Rico, there is no concrete evidence that this is true for Xalatan. Indeed, there is no evidence about where Xalatan is made. Therefore, Xalatan is classified as inconclusive as to whether it is manufactured in the U.S. The manufacturing data column for Xalatan is empty, as no data was found.

7.7.3. Gliadel – Arbor Pharmaceuticals

Subject invention three, Gliadel, is sold by Arbor Pharmaceuticals and treats adult patients with newly-diagnosed high-grade malignant glioma as an adjunct to surgery and radiation. Arbor Pharmaceuticals, a subsidiary of Azurity Pharmaceuticals, acquired the rights to Gliadel from Esai in 2012. Esai still manufactures the drug at its manufacturing location in Baltimore, Maryland, which is the global manufacturing site for the Gliadel wafer. I found manufacturing location data for Gliadel on Esai's current website. The data is in the form of website information.

7.7.4. Clolar – Genzyme

The fourth subject invention, Clolar, is sold by Genzyme and is "a cancer medicine that interferes with the growth and spread of cancer cells in the body" (drugs.com 2022). In the search for the manufacturing location of Clolar I found information in a 2008 10K form that Genzyme contracts out manufacturing and fill-work for Clolar. Contracting out manufacturing means that it is impossible to find the true manufacturing location for Clolar. Unfortunately, the 10K form is 15 years old so the information may not still be accurate. The manufacturing data for Clolar is in the form of a government document, and the drug is classified as inconclusive as to whether it is manufactured domestically or not.

7.7.5. Atripla, Emtriva and Truvada - Gilead

The subsequent subject inventions Atripla, Emtriva and Truvada are all sold by Gilead, which according to its 2017 10K filing uses third-party contracting to make all of its pharmaceuticals. All three drugs are used to treat HIV. The company's use of third-party contracting makes it impossible to trace where the products are made. I found no other information available online that had any other statements on the manufacturing location. Therefore, I classified these subject inventions as inconclusive results, where the data is in the form of a government document.

7.7.6. Menostar – Bayer Corporation

The eighth subject invention, Menostar, is sold by Bayer Corporation. Menostar is a female hormone drug used to treat bone loss after menopause. According to Drugs.com, which lists drug information online, Menostar is manufactured by Kindeva Complex Drug in Northridge, California. This information was only found by looking closely at the pictured drug label posted on Drugs.com, which states that Kindeva Complex Drug manufacturers Menostar. It's unsure when this label was posted on the site, so the year of information is set to 2023. The data for Menostar is in the form of website information and is domestically manufactured.

7.7.7. BiDil – Arbor Pharmaceuticals

The ninth subject invention, BiDil, is sold by Arbor Pharmaceuticals. The highly controversial and discussed drug is the "first drug approved by the Food and Drug Administration marketed for a single racial-ethnic group, African Americans, in the treatment of congestive heart failure" (Brody and Hunt 2006). According to Drugs.com, BiDil is manufactured by Lannett Company, Inc. in Philadelphia for Arbor Pharmaceuticals. The information seems to stem from 2020, being fairly recent. The manufacturing data for BiDil is therefore classified as website information, and manufactured domestically in the U.S.

7.7.8. Relistor – Salix Pharmaceuticals

The last subject invention, Relistor, is sold by Salix Pharmaceuticals. Relistor is used to treat constipation in adults that is caused by prescription opioids. According to a 2013 10-K form Salix Pharmaceuticals does not own any manufacturing facilities, but rather uses a third-party contractor. As stated in the 10-K form, Relistor SI in a vial is produced in Greenville, North Carolina. The Relistor SI pre-filled syringe is manufactured in Ravensburg, Germany. The

main component for both products is produced by Mallinckrodt Pharmaceuticals in St. Louis, Missouri. Thus, Relistor is partially manufactured in the U.S., and manufacturing data is in the form of government document.

I screenshotted each site that contained valuable information and put the screenshots into a folder for the drug I was researching, with website URLs noted down. In the end, after doing all the research on each drug and its manufacturing location I completed the excel spreadsheet. I then created a similar, easier to read spreadsheet to show my results, pictured below. My dataset was then complete, with as-could-be precise data that would allow me to answer my research question

Table 3: Original dataset of the domestic manufacture of federally funded (NIH) subject inventions from 1980 to 2007.

Drug name	**Commercial name**	**Assignee**	**First patented**	**Current marketer**	**Manufactured in the U.S (Yes/No/Partially/Inconclusive)**	**Comment**	**Year information**	**Document type**	**Patent number:**	**Price per product**
Pregabalin	Lyrica	Northwestern University	2004	Viatris (formerly Upjohn, a Pfizer company)	Yes	Puerto Rico	2021	News article	6197819	$266 - 1,112
Latanoprost	Xalatan	Columbia University	1996	Viatris (formerly Upjohn, a Pfizer company)	Inconclusive	Viatris manufactures in Puerto Rico, but no evidence that concretely proves Xalatan is manufactured there.		No data	4599353	$274
Carmustine	Gliadel	MIT	1996	Arbor Pharmaceuticals	Yes	Baltimore	2022	Website information	4757128	$4,638
Clofarabine	Clolar	Sloan-Kettering/Southern Research Institute	2004	Genzyme	Inconclusive	Contract out manufacturing and fill-finish work.	2008	Government 10-k form	4918179	$3,763
Efavirenz; emtricitabine; tenofovir disoproxil fumarate	Atripla	Emory University/Yale University	2006	Gilead	Inconclusive	Third-party contractor, impossible to find where location is	2017	Government 10-k form	7402588	$3,163
Emtricitabine	Emtriva	Emory University/Yale University	2005	Gilead	Inconclusive	Third-party contractor, impossible to find where location is	2017	Government 10-k form	5210085	$574

Emtricitabine	Truvada	Emory University/Yale University	2004	Gilead	Inconclusive	Third-party contractor, impossible to find where location is	2017	Government 10-k form	7402588	$1,949
Estradiol	Menostar	U. of California/Kaiser Health Plan/Permanante Medical Group	1997	Bayer Corporation	Yes	Manufactured by Kindeva Complex Drug in Northridge, California.	2023	Website information	5891868	$180
Hydralazine and isosorbide dinitrate	BiDiL	U. of Minnesota	2005	Arbor Pharmaceuticals	Yes	Manufactured by Lannett Company, Inc. in Philadelphia.	2020	Website information	4868179	$421
Methylnaltrexone bromide	Relistor	U. of Chicago	2010	Salix Pharms	Partially	Salix owns no manufacturing facilities, therefore use third-party contractor for manufacturing, which manufactures domestically.	2013	Government 10-k form	6559158	$2,444

8. Discussion of results and analysis

8.1. Results from the original dataset

The results from creating the original dataset show that only *ten of the ninety drugs, or 11%*, are subject inventions that fall under section 204 of the Act. The number may seem surprisingly small. However, section 204 is written so that most federally funded products are not subject inventions, and therefore not subject to section 204.

Further, out of the ten drugs that are subject inventions, I could only find evidence that four were made in the US: Lyrica, Giladel, Menostar and BiDil. This evidence of domestic manufacturing is concrete, recent, and trustworthy as it is at most three years old and from reliable internet sources. Relistor is partially manufactured in the U.S., with production in North Carolina and Germany, and therefore it is the only drug that is labeled partially manufactured in the U.S. However, the information on Relistor is a decade old, so it is unclear how accurate this information may still be.

The five remaining drugs were all labeled inconclusive. First, Xalatan was deemed inconclusive due to lack of data concretely proving the drug's manufacturing location. As mentioned earlier, Viatris manufactures many of their pharmaceutical products in Puerto Rico, which is probably further fueled by their tax exemption grant which is written in their 10-K form. However, there is no concrete evidence proving Xalatan is also manufactured there, despite extensive effort to find any. Thus, it is shown as inconclusive.

The four remaining subject inventions - Clolar, Atripla, Emtriva and Truvada - are all manufactured by a third-party contractor. When companies use third-party contractors, it is impossible for researchers or anyone without inside information to know the true manufacturing location for those products. Without knowing the manufacturing location, all four were labeled as inconclusive.

8.1. What the results of process tracing the causal mechanism tell us

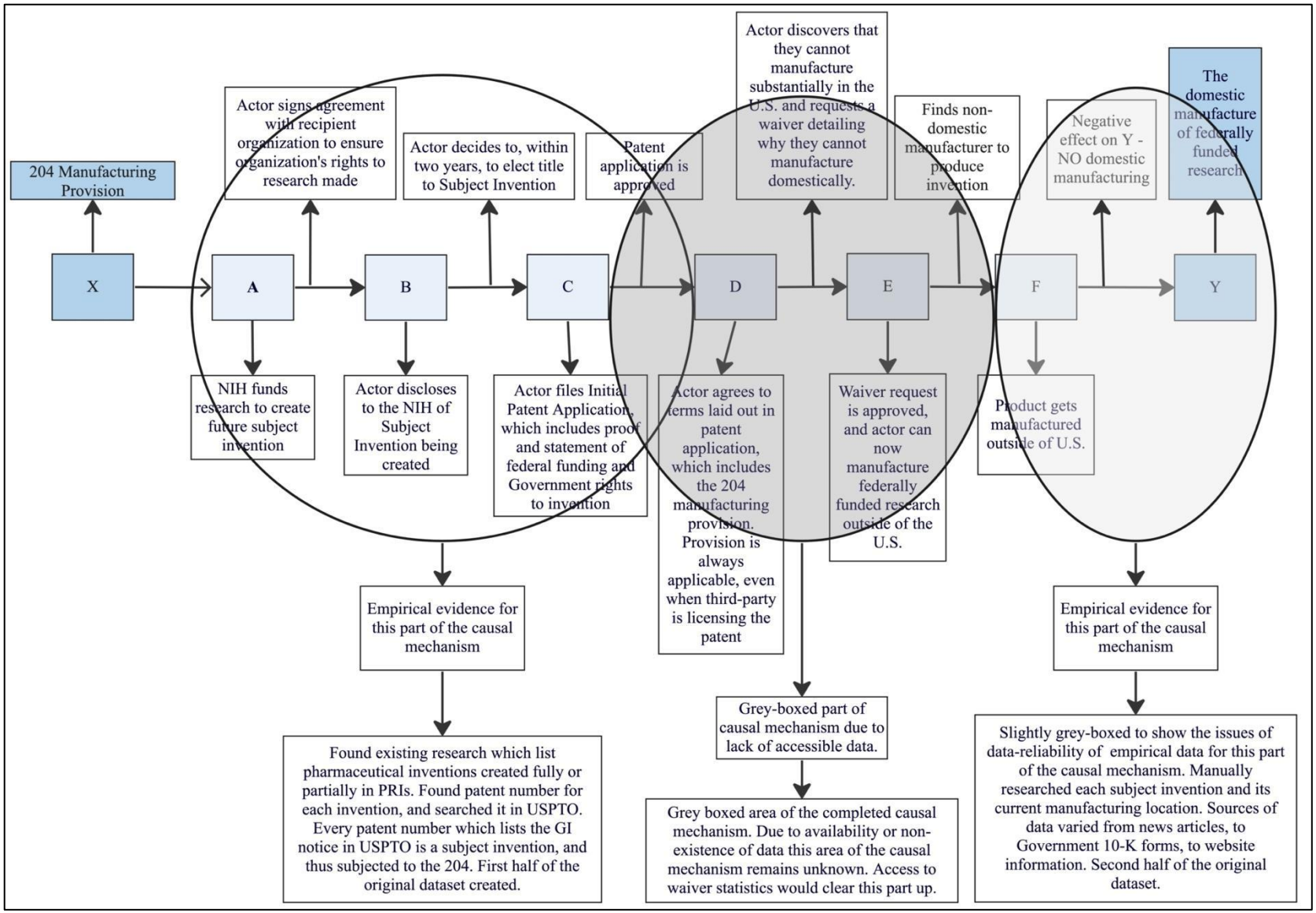
The CM for how X affects Y was a black box when I started this thesis. To unpack the black box of the CM for section 204, I dug through the Act's legislative history to find out how legislators believed section 204 would affect domestic manufacturing. The only mention of

section 204 or similar was in Senator Bayh's analysis of the provision. The identified CM was simple, and did not adequately explain the events, activities and actors that contribute to the cause of Y. I therefore further theorized this found CM into a more complete CM. Further, I explained both the causal events that cause X to have an effect on Y and the causal activities of actors and events. Finally, I used the method of process tracing as a basis for detective work and collected empirical evidence for each causal event. Figure 8.1 reflects that process.

Figure 8.1. presents the original research contribution of this thesis, which unveils the "black-boxed" CM of section 204 and the accompanying empirical data for nearly all events. The empirical data for events A, B and C is strong. The article by Stevens et al. lists all inventions created partially or wholly in PSRIs from 1980-2007. The article is peer-reviewed and therefore a credible source. To find each patent number I used a patent number search program. Each patent number was searched in the USPTO, a U.S. government patent database, which is also a strong source. Those that had a GI notice were subject inventions, which is established in the Patent Application, event C. As shown in Figure 8.1, events D and E are grey boxed. Although the CM is theorized in a way that explains the causal chains and links, there is no accessible data for the events, thus the empirical data for these events are unknown. Unveiling this part of the CM would increase the validity of the CM of X on Y, as well as any found effects of X on Y.

Events F and Y are also very slightly grey-boxed. There is a thorough theorized CM and there is accompanying empirical data for the events. However, the empirical data found for F and Y are weaker, which is signified by being slightly grey-boxed. Only four subject inventions could be empirically verified as being fully domestically manufactured in the U.S., with all data from 2020 or more recently. One was partially domestically manufactured in the U.S., with a data source from 2013. The rest were deemed inconclusive due to the lack of data, primarily because the drug owner used third-party contractors for manufacturing. Further, the source for the data was older for the drugs labeled as inconclusive.

Figure 8.1. Visual explanation of empirical data for the causal links.



Based on these results from the research, we can to some degree, based on the verifiability of the empirical data found for each cause in the mechanistic process of creating an outcome, determine that there is a possible causal mechanism between X and Y, where the outcome is inconclusive due to the data.

Without accessible data there is no definitive way to determine the policy effects of section 204. For example, I could only find evidence of the site of manufacture for five of the ten subject inventions, and the data for the fifth was a decade old. If I had found evidence of the site of manufacture for more than half of the ten subject inventions, I could perhaps determine X's effect on Y with more empirical certainty.

More broadly, it was extremely difficult to process trace and empirically verify each of the causal events. Most of the data is behind closed doors at the agencies. The data that is accessible is well hidden. This lack of reporting, transparency, and publicly available data seems to be an inherent flaw in the law.

Equally importantly, only ten of the ninety drugs created with federal funding were subject to section 204's "manufactured substantially" requirement. Though these ninety drugs are just one sample of a much larger group of inventions created with federal funding, at a minimum these results raise questions about whether section 204 has had a real impact on domestic manufacturing. At most, if these results are extrapolated to cover all inventions created from FFR, the measurable scope of section 204 is only roughly five percent of the total.

Based on these results, I argue that section 204 contains multiple loopholes and flaws. To support this argument, I will use the documents and findings from the DOE presented earlier in this chapter.

8.3 Interpretation and analysis of the DOE DECs and their relation to the dataset results, and to the NIH – closing existing loopholes

8.3.1. Comparing DOE to the NIH on implementation of the Act and section 204 – what can we learn?

DOE places a high priority on inventions. The agency's mission is to "ensure America's security and prosperity by addressing its energy, environmental and nuclear challenges through transformative science and technology solutions" (Department of Energy n.d.). Thus, DOE's federally funded inventions are not only important for technology innovation, but also for national security and domestic supply chains.

The same could be said of the NIH and the inventions created with federal funding through it. Not only is the NIH a great contributor to the creation of new medicines and pharmaceuticals, but the agency also is responsible for the success of several health technology industries (Mazzucato 2013, 66).

These two agencies have arguably equal importance to the well-being of the public and the country as a whole. One agency, the DOE, ensures that there is a domestic energy industry, based on innovation of technology critical to American infrastructure and national security. The other, the NIH, is responsible for finding solutions to public health, is "the steward of medical and behavioral research to the nation", and the application of that knowledge to "enhance health, lengthen life, and reduce illness and disability".

The Act's legislative history reveals that one reason for passing it was to implement a uniform patent policy. However, as shown below, DOE has had a radically different approach to section 204 than the NIH.

8.3.2. DOE, the DECs and how they relate to the thesis topic

The DOE has issued ten DECs in the forty years the Act has been in effect. Out of the ten, four - nearly half - are related to the manufacturing of federally funded products. This indicates how important manufacturing is not only to the energy industry but also to DOE.

DOE's series of manufacturing-related DECs show that the agency identified and tried to address problems with section 204 through a series of progressively broader decisions. The first of these DECs, in 1985, highlights the continuing importance of domestic manufacturing of FFR, only five years after the Act's passing. In the second DEC, from 2013, DOE found that there were exceptional circumstances for exclusive licenses from federal funding in projects involving "energy efficiency, renewable energy, and advanced energy technologies …to better promote U.S. manufacturing" (Department of Energy 2013). The 2013 DEC also introduces a new requirement of U.S. Manufacturing Plans, to be incorporated into funding agreements so as "to better meet the objectives of Bayh-Dole, which include the goal of promoting commercialization of inventions by United States industry and labor".

In the third manufacturing-related DEC, issued in 2020, the DOE determined that there was an exceptional circumstance and created a U.S. Competitiveness requirement for patent rights to quantum information technology derived from federal funding. This requirement expands the scope of the 204 provision by subjecting all inventions, not just subject inventions, to the provision. This is to ensure more domestic manufacturing. The purpose was to "better promote U.S. Competitiveness and protect critical national interests in U.S. leadership in QIS". These critical national interests included "U.S. national security and economic interests, such as U.S. manufacturing, while maintaining the rights of small businesses and non-profit organizations to commercialize their federally funded inventions".

The DOE issued its most recent and significant manufacturing-related DEC in 2021. This DEC extended the U.S. Competitiveness requirement to cover *all* inventions derived from research funding contracts with the DOE. By doing this, DOE extended section 204, which only applies to subject inventions, to all inventions derived from federally funded research. This gave DOE the ability to regulate and oversee the manufacture of federally funded inventions at a much larger scale than the original Act. Under this DEC, section 204 doesn't just "maximize the probability" of domestic manufacturing of subject inventions, but rather *ensures* domestic manufacturing of all inventions derived from federally funded research via DOE.

8.3.3. What conclusions can we draw from DOC's DECs?

Through its DECs, DOE has taken a radically different approach to the implementation of section 204 as compared to NIH. DOE now effectively requires domestic manufacturing for all inventions made from funding it provides, while the NIH grants all requests for waivers of the Act's domestic manufacturing requirement (Struver 2016).

This difference in agency action tells us that there is more than one way to interpret the Act. It also tells us that agencies can exercise quite wide discretion on the enforcement of the Act's "substantially manufactured" provision. Finally, we can infer that DOE has not found section 204 to be sufficient to drive domestic manufacturing of inventions created from DOE funding. We can infer this because otherwise DOE would not have issued DECs that require these inventions to be made in the US. Section 204 would have been enough.

8.3.4. The paradox of section 204: loophole upon loophole

To walk back to Bayh-Dole basics, the Act has public good provisions beyond section 204 that ensure the citizens' "rights" to federally funded research. Specifically, the government has the "march-in" right which allows the government to "march-in" and "assume ownership rights of intellectual property when specific provisions of the Act have not been fulfilled, particularly, failure to take necessary steps to achieve practical application of the subject invention" (Henderson and Smith 2002, 3). Although the law specifically mentions practical application, it also states the discretion of the federal agency to use the march-in for other provisions in the Act, also section 204.

The government can use the march-in right when it is "necessary to alleviate public health or safety needs" and when it is "necessary to meet the public use requirements specified by federal regulations" (Rein, Zalcenstein and Nangia 2017). 203(a)(3), allows for march-in when "action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor" (Bayh-Dole Act of 1980). And section 203(a)(4) allows for march-in if the grantee "has not substantially manufactured the product in the United States" (Rein, Zalcenstein and Nangia 2017).

However, the march-in provision does not have much significance as a public good provision. For example, though section 203(a)(4) of the Act gives agencies the right to march-in if they have found a violation in any of the section 203 sub-laws, the Department of

Commerce has issued a regulation that allows agencies to reject march-in even if they find march-in conditions (37 CFR Chapter IV –Department of Commerce).

8.3.5. The context for the CMs of the Act and its effect on innovation

The political historical context for the passage of Act is summarized in Table 4. The main contribution of this context is: the public vs. private debate is not new and neither are the public good provisions. In fact, it has been a lasting political issue. Further, the government contribution to science is also not new. Pharma is an industry that has had incidents of price fixing of lucrative products. Pharma is clearly a lucrative industry. Those that profit from pharma and governmental funding of pharma, as well as supporting actors, benefitted from the implementation of the IPA program. The program also represented the first shift in public vs private ownership of FFR. Then, because the program was lucrative for the actors involved, a lobbying process began to implement further private takeover of the rights to FFR. Opposing arguments were concerns this would raise the cost of healthcare. The IPA programs were nonetheless favored, innovation became a critical political issue, and with much debate the Act was passed in 1980.

Table 8.3.5. (1): Chronological list of events for the political historical context of X on Y.

Year	Events
1945s	Debate of private vs public ownership of FFR since post WWII. Kilgore and Bush dominated each side of debate, the first arguing against the "giveaway" of rights to large corporations. The latter argued retaining titles was important for incentive to participate in FF R&D. Thus, each "side" of the debate or the issue changed much.
1950s	Pharma grew exponentially.
1959 - '60	Kefauver went after pharmaceutical drug pricing, confident that Pharma had been fixing prices on lucrative drugs.
1962	Kefauver proposed corrective legislation; passed in 1962. Gave FDA the authority on drug efficacy, safety, and uniform generic drug names.
1963 - 60s	Norman Latker was hired by the NIH to run HEW in 1963; changed the course of university patenting. Pushed HEW to change its patent policy in the 60s.
1968	Harbridge House Report published. Contributed to the shift from public ownership. Source of "28 000 unused patents". Spurred increased debate on public vs private. The arguments were the same as it were after WWII, although the Government had long been investing and financing successful drug and vaccine programs.
1968	Introduction of IPA programs by Latker, changed the patent system for FFR permanently. Approved 90 percent of petitions for title between '69 and '74. Established ownership transfer without law.

1976 –	Califano Secretary of HEW and dismantled the IPA program. Was opposed to giving away the government. patent rights. Was concerned that "that the university patents and licenses could contribute to higher health-care costs". Latker vehemently opposed this, conflict ensued.
1976 – 1980	Universities were upset with HEW and "discontinued" IPA programs. Lobbied heavily for the passage of an Act-like law, as well as early AUTM in collaboration with Latker. Dole held a press conference in '78 claiming HEW was stonewalling. Issues with the U.S. declining role in innovation and foreign competition, allowed the Act to pass in 1980. The Act allows private research institutions and small businesses to patent FFR.
1983	Norman Latker drafts and writes President Reagan's Presidential Memo which also allows large, for profit corporations to also patent FFR.

With this context in mind, there will be a brief analysis of the CMs related to the Act and innovation. Table 5 presents the general CMs argued during the hearings prior to the enactment of the Act. Table 6 presents the general argued CM for how the Act has caused innovation. These are found in Mowery et al. book the Ivory Tower, and represent the general CMs argued twenty years after the enactment of Act. Table 7 exhibits the alternative CMs Mowery et al. found in their book, also about twenty years after the enactment of Act.

Table 8.3.5. (2) Causal mechanisms argued by pro-Act witnesses during hearings prior to the Act for how patents will affect Innovation.

X – Cause and IV	**CM - Causal Mechanism**	**Y – Effect and DV**
Small business retains patent rights (X) →	→ commercialize the product → greater product →	innovation (Y) would be achieved in the American marketplace
Giving patent rights (X) →	to the private sector would encourage private industry and thus	More innovation (Y).
Lack of patent rights (X)	acted as a disincentive for many small companies to participate in the federal R&D process, resulting in a	decline in private sector innovation (Y) over the last decade (1970s).

Table 8.3.5. (3) General argued causal mechanisms for Act on Innovation.

Cause and IV	**CM - Causal Mechanism**	**Y – Effect and DV**
Act	Economy and innovation.	Increased university patents and licensing.
Act	Increased university patents and licensing.	More university research into "New Economy" during 1990s

Table 8.3.5. (4) Alternative causal mechanisms by Mowery et al. in Chapter Five.

Cause and IV	**– Causal Mechanism**	**effect and DV**
Advancements of molecular biology	Growth in 70s and 80s grew on R&D from federal funding in basic science and biomedical science that started in the 60s.	Patenting and licensing growth (in concentrated areas).
Decisions by the judicial and patent office	Made decisions that clarified and broadened the range of patentable content in biomedical science. Patent policy.	Academic patenting and licensing growth.

Supporters of the Act are convinced that the Act has promoted innovation. A comparison of the causal arguments and mechanisms from before the enactment and twenty years after show that not much changed. Even so, it is still regarded as a large success, as argued through in the AUTM report of academic licensing contribution to the economy. However, Mowery et al.'s research demonstrates that the CM between the Act and innovation is much more complex than one may otherwise think. This is also confirmed by Mazzucato in the book *The Entrepreneurial State.* Further, the effect on the Act in regard to innovation is only applicable to concentrated areas of research. As well, universities had long been patenting and licensing prior to the Act, being on a steady curve since the 40s and did not have a sharp break after the Act. Since the Act was found to not have the major effect on innovation as argued by Act supporters, one can assume the same goes for the 204 provision. If the Act in itself isn't necessary that impactful, how can one expect that the 204 provision will?

8.4. Concluding thoughts – wrapping up loose threads

This thesis asks whether section 204 of the Bayh-Dole Act drives manufacturing of federally funded inventions in the U.S. After researching the manufacture of NIH-funded pharmaceuticals, the answer is: *It is hard to tell*. Because of the way section 204 of the Act is written, and the way NIH interprets it, it is hard to tell whether section 204 has had an effect on the domestic manufacture of pharmaceuticals in the U.S. Moreover, an important part of the CM is still grey-boxed.

The lack of publicly available data on the effects of section 204 may indicate that the Act is a kind of public value failure (PVF). As discussed earlier, PVF occurs when "private individuals or institutions exercise rights that are the exclusive privilege of government, such as speaking on behalf of the whole of society or making law and regulations to protect the public interest" (Valdivia 2011, 39). A major argument for the Act was that the Act would

give a real return to the public for the investment of public funding in research (96 U.S. Congress, Senate, Committee, S. 414, 1). Without public data on the implementation of section 204, there is no real way for the public to determine whether the 204 provision really has an effect on domestic manufacturing. A public value failure also occurs when there is a lack of transparency in the way the Government does policy (Valdivia 2011, 40). As Valdivia points out, "the passing of Bayh-Dole was enacted in a public and transparent fashion, but its implementation is not as transparent" (Valdivia 2011, 41). This corresponds with the findings of this thesis.

There is other evidence that the Act has produced PVFs. The NIH has "received six march-in petitions and has denied each one", mostly on the grounds that march-in was not necessary to reduce pharmaceutical prices (Thomas 2016, 1). Most recently, in March 2023 the NIH denied a petition filed seven years ago by the Union for Affordable Cancer Treatment to reduce the price of the federally funded created drug Xtandi, which treats prostate cancer (Schwartz 2023). Lobbyists, including the AUTM, lobbied NIH to reject the petition, "claiming that march-in rights would not be an effective means of making the drug less expensive, but would seriously erode the fabric of the U.S. innovation ecosystem" (Schwarts 2023).

Out of the bestselling drugs of 2019, three of the drugs were created with federal funding. Each drug rose in price between thirty to eighty percent between 2014-2019 (I-MAK 2020). However, despite this tension between federal funding, public goods, and high prices, Senator Bayh and Dole have repeatedly stated that the legislation "march-in provisions were never intended to be exercised for price-control reasons, rather, they were primarily designed to intervene if licensees were failing to take specific steps to license their innovations" (Ezell 2020).

Although Senator Bayh and Dole say that the Act march-in provision was not created for purposes of price-control, one can argue that it is within NIH's public health mandate to march in to ensure that the public can afford medications it needs. Indeed, the march-in provision states that the agency can march-in to "alleviate public health or safety needs" (Bayh-Dole Act, Public L. 96-517, 1980).

9. Conclusion

This thesis attempts to answer the research question "*Has the Bayh-Dole Act of 1980 and its 204 "substantially manufactured" provision contributed to the domestic manufacture of federally funded inventions at the NIH*?". In answering this question, the thesis makes three original contributions to research: Making sense of the Act and its mechanisms of causality, exploring how to investigate the effects of the Act and, in the process, creating an original dataset; and assessing whether the Act has had consequences and why or how the CMs would potentially explain these consequences. Most of these questions involved unknown territory; some of the answers attempt to fill a scholarly gap.

The most important goal of the Act relevant to this thesis is to "promote the commercialization and public availability of inventions made in the United States by United States industry and labor". As discussed, there was only one mention of section 204 and domestic manufacture in the Act's legislative history. Section 204 was designed "to maximize the probability that the jobs created through the commercialization of new products and (…) inventions will benefit American workers". The only found CM between the Bayh-Dole Act and domestic manufacture of FFR was very simple.

The CM of section 204 is equal in simplicity to the general causal arguments of how the Act would affect innovation. As shown by Mowery et al.'s research, the CM for the Act on innovation is not only much more complex than one would think, but the effect of the Act is concentrated in specific research fields. Further, universities were long active with patenting and licensing prior to the Act. However, many believe that patents are crucial to innovation. As explained in chapter five, innovation theory is widely used for this belief. But as Mazzucato argues, the road from patent right acquisition to commercialization is incredibly complex. Thus, the argued CM for the effect of both the Act and section 204 does not adequately explain exactly how the Act would increase innovation or how section 204 would increase the domestic manufacture of FFR.

In this thesis I have further theorized the simple CM for how the Act 204 provision (X) would have an effect on domestic manufacturing (Y). I also used detective-like methods to trace empirical data for most of the causal events and links. The acquisition of data was

challenging, which highlights a major issue of the Act and section 204: Transparency and lack of information that would enable us to measure the Act's effectiveness.

By identifying, tracing, collecting and organizing I have created an original dataset of the manufacturing location of subject inventions created with FF at the NIH from 1980 to 2007. The first half of the original contribution of research was the identification of which inventions were subject inventions. The second half was researching true manufacturing locations of the subject inventions. The result was that out of ninety drugs, only ten were subject inventions created after 1980. Further, I could only confirm that five percent of the subject inventions were made in the US. The rest were inconclusive due to data gaps. .

As explained above, it is unclear whether section 204 has the intended effects on domestic manufacturing. We don't know for sure, because there is no recent, verifiable, non-secret data that could tell us whether X has an effect on Y. We can confirm to some degree, based on the verifiability of the empirical data found for each cause in the mechanistic process of creating an outcome, that there is a possible CM between X and Y, where the outcome is inconclusive due to the data.

To return to the start of this thesis, there is a lot at stake in the ownership of federally funded research. Before the Act was passed, the federal government mostly owned the rights to federally funded research. After 40 years of the Act, the US has a world class pharmaceutical research complex worth hundreds of billions of dollars, as well as some of the highest prescription drug prices and worst public health outcomes of any developed country (Buchholz 2022). Prescription drug manufacture has mostly moved overseas (Huang 2020).

My thesis question asked whether one of the Act's public good provisions, meant to justify this transfer of rights from public to private actors, was working as intended. The answer is: We don't really know, and we don't really know because there is very little publicly available data to assess the public good effects of the Act. This seems like a very large gap in a very important piece of public policy. I hope that future researchers will follow it up.

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