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論 文 題 目： Network Indicators of Japan's Academics' Value-adding Practices from Their Intellectual Capital: Insights from Pharmaceutical Industry Commercialization Data
日本の学術機関の知財価値創造に関するネットワーク指標：
製薬産業の知財商業化データを用いた考察

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要　　旨：

Today, public research institutions' scholars in Japan commercialize their intellectual capital (IC) dedicatedly by utilizing collaborative research, sponsored research, and intellectual property (IP) commercialization. Marketing intellectual capital was not new in 1998, but the rules governing it changed to make that process evolve. Though dissemination of academics' IC was not new, policy change embodied in several new laws that came into effect in Japan between 1998 and 2004 and were based on precedent-setting American legislation (the Bayh-Dole Act), were meant to change academic inventing practices to incentivize the academics' adding of value to their research output. Together, the 1998 Law to Promote the Transfer of University Technologies, the 1999 Law of Special Measures to Revive Industry, the 2000 Law to Strengthen Industrial Technology, and the 2004 National University Corporation Law aimed to alter dissemination practices, making invention a generator of revenue for academia and, so, incentivize dissemination for universities and their researchers. However, it is not known, from looking at the researchers' practices themselves, if that change in practice occurred. It is unknown if the incentives worked. This dissertation employs a previously unutilized source to find out, using like results from America's national innovation system to provide explanatory comparisons that explain Japan's academics' co-patenting practices.

Using a United States' (US) data source to test Japan's results seems inappropriate, but several advantages make it preferable to Japan's sources, even for testing Japan's results. First, note that the data sources include the drug approval text of the United States Food and Drug Administration (USFDA), patents registered in the United States Patent and Trademark Office (USPTO), and various academic and professional sources that identify inventor's employment affiliations. USFDA data offers a longer timeframe than Japan sources. Uniquely, America's patent law has, until the Leahy-Smith America Invents Act was enacted on March 16, 2013, identified actual inventors as retaining patentee rights. It did not employ a first-to-practice in country system, so legally defined any real inventor as a patentee. In the US, "patentee" and "inventor" are legally synonymous. Second, given the expensive, risky, and highly regulated nature of worldwide drug markets, its high upfront costs, maximum worldwide dispersal of sales maximizes sales to offset the high costs of research and development (R&D), extensive legal limits enforcing safety and inhibiting profiteering, and a foreshortened window for monopoly profit-taking between the end of the lengthy, trials-based approval process and the end of patent protection, which is the point

when generic drugs are allowed to compete in the marketplace, pharmaceutical firms market globally. In this last respect, Japan and US data sources should be equally applicable, since, as shown by Grossman and Lai, market size is the chief determinant of R&D investment. US drugs go to Japan. Japan's drugs go the America. Thus, US sources are equal or more accurate and complete than Japan's Food and Drug Administration and the Japan Patent Office, even for drugs sourced from Japan.

Using these data-sources for the analysis presented in this dissertation offers two novel features. First, it revisits Dr. David C. Mowery's and others' criticism of the value of the Bayh-Dole, but considers it in a novel way by adapting Dr. Bart Nooteboom's supplier innovation network theory to quantitative data on co-patentee group-forming practice. Supplier innovation network theory is particularly applicable to analysis of proportions of co-patentees by affiliation, because both measure the speed of innovation as a value-adding factor. Second, this dissertation also employs a heretofore unused data-source, USFDA drug approvals data, to identify innovations. These are true innovations, not proxies, as are the patents and citations that are commonly used to identify innovation. Less new, but equally important to this dissertation's examination is a third axis, which considers Japan. Specifically, Japan's performance as an innovator is in question. Dr. Fumio Kodama who attributes Japan's performance to synergies between market rewards and socio-cultural factors anchors one side of the debate over whether Japan is performing well or poorly. Dr. Robert Kneller conveys the opposite view when noting that Japan underperforms in broad business metrics of efficiency and effectiveness relative to international competitors due to deficiencies in its governance, legal oversight, and administration, among other contentions. The new data-source and adapted perspective add to legacy literature examining academic innovation in general and Japan's in particular.

Regarding the data and analysis, proven innovations' academic co-patentee behavior has not been well-employed. This research does. It bolsters the study of co-patenting behavior by using a population, not sample, of quantitative micro-economic source data. Further, that data is completely blind to research into policy changes' impact on that behavior. It is original scholarship in the otherwise crowded area of research into the management of technology innovation.

This dissertation fills that gap in the legacy literature by building such a database and using it to macro-economically find how drug innovations' inventors' affiliations populate co-patentee networks. Tests occur on either side of a policy change that incentivizes researchers affiliated with academia differently from others. Policy of Japan's national innovation system is the true subject of this analysis, but US results are used for comparison since its Patent and Trademark Law Amendments Act (December 12, 1980), called the Bayh-Dole Act, was the model for Japan's equivalent set of four coordinated laws, but principally the Industrial Revitalization Law (Japan's Bayh-Dole). Innovation management policies of both Bayh-Doles directly incentivize the selling of academics' intellectual property, but also indirectly promote broader intellectual capital commercialization by academia. Thus, this dissertation's hypothesis asks whether co-patentee networks' composition indicates that Japan's academics' practice of transferring intellectual capital to drug commercializing firms was changed by the Industrial Revitalization Law.

One man's decision: it is the basest observable measure in micro-economic theory. This research starts there. Adding up every (a) networking decision of each Japan- and

US-based patentee of (b) each patent of (c) each drug innovation for the American market determines how policy change affects one man's decision about how to manage his inventiveness within a community of fellow inventors. Motivation for decisions' effects is to maximize potential value. Since Japan and the US set the same law, a Bayh-Dole Act type allocation of IC and IP rights to universities, but the US 19 years earlier, comparing its with Japan's academics' networking decisions before and after its Bayh-Dole shows if their behavior is changing to reflect the US model. Thus, each man's decision on co-patentees aggregates to a macro-economic answer to the broad research question: how do rule changes evolve innovation practices? This leads to the narrower question of the hypothesis: does co-patentee networks' composition indicate that Japan's academics' practice of transferring intellectual capital to drug commercializers was changed by Bayh-Dole?

The exact hypothesis is as follows: pharmaceutical industry commercialization data show network indicators of Japan's academics' value-adding practices from their intellectual capital demonstrate that introduction of Bayh-Dole-type administration to Japan's national innovation system results in no detectible change in pattern of network dynamics that constitute a value-adding practice. This uses network indicators of drug innovations to answer if Japan's reforms' had any impact.

Principally, this essay looks at Japan's academics' inventor networking practices' evolution after Japan's Bayh-Dole. It compares non-national universities' academics' behavior before April 1, 1999 and 2004 for national universities with those from then onward. On those dates, the new policy began being applied. However, meta-analysis restricts analysis, so Japan's Bayh-Dole era innovation practice is also compared with America's. Pharmaceutical industry data are used to say whether academics' potential for adding value is working in either country. The practice of retaining intellectual property development research adds value by reducing its buyers' risk; retention is measured by the proportion of academics among inventors. Since patents define the limits of a network of inventors (co-patentees), the patent level of analysis is used. Effects which are exogenous to micro-economic co-patentee group formation, like affiliation of assignees, time effects, size of co-patentee groupings, and speed of patenting, are tested to determine their impact on the core analysis of proportion of academic co-patentees resulting from Bayh-Dole. Findings suggest that Bayh-Dole type legislation has registered no significant impact on academic inventors' research-for-inventing behavior in Japan.

The methodology of analysis includes three elements: composition of the database from source data, attribution of weights for clarifying the roles of exogenous variables on co-patentee networks' affiliative composition, and comparison of affiliative composition of co-patentee networks by difference of means analysis on axes of national innovation system (Japan versus the US) and of policy (before versus after the Bayh-Dole type laws were enacted). Database composition began by identifying drug innovations using the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, which is published by the United States Food and Drug Administration's Center for Drug Evaluation and Research. It identifies innovations, since innovations are defined by the Organization for Economic Co-operation and Development (OECD) as including commercialization. From 1982 to the present, it also identified innovations' patents, which were traced in the United States Patent and Trademark Office database to find their patentees, assignees, and dates. Named patentees and assignees were traced in academic publications and

professional literature and news to determine affiliation: public or private in the period prior to patenting. It is from this tri-sourced database that co-patentee affiliations are reported. Exogenous factors accruing from time, number of co-patentees, speed of innovation, and assignee affiliation were tested for applicability to weighting and only assignee affiliation was found applicable. The weighted proportion of public co-patentees was tested for difference of means both between countries and between pre- and post-Bayh-Dole periods. Crosswise comparison of results found that, for academic co-patenting, Japan and America were different before, but indistinct after their country's Bayh-Dole and that the US did change after Bayh-Dole, but Japan did not. Thus, given these crosswise comparison's derivations, Japan's academics' co-patenting network behavior showed no sign that added incentives resulted in their hording the inventive process arising from the Industrial Revitalization Law.

From similar law and marketplace objectives initiated near twenty years apart, Japan's and America's national innovation systems appear to exhibit the same conclusion. It is that Bayh-Dole type law failed to proactively change Japan's academic inventors' networking for innovation, most clearly shown by analytical results showing that America's post-Bayh-Dole transformation has accommodated practices that are statistically similar to Japan's pre- and post- behavior. Drugs' patents' inventors' professional affiliations provide a novel, blind, and quantitative framework for finding how much value academics can earn from their intellectual capital, since composition of co-patentee affiliation at the time of patenting indicates the labor needed to get there. Results show no discernible change in how Japan's academics innovate. Pre- and post-Bayh-Dole/Industrial Revitalization Law cross-comparisons between US and Japan academics' co-patenting networking concludes that Japan's academics' inventive capacity was not transformed by its national innovation system's policy change.

Japan's Academics performance did not show America's turn. Clearly, analysis by difference of means shows that no difference developed. Given the dynamic change in the US system, the easy conclusion is that Japan's law failed to overcome path dependent behavior by its academics and the cultural norms from prior to the law being enacted were retained. Kodama suggested that this should be true (Kodama, 1995), given his ascription that culture changes slowly and is somewhat randomly favored or disfavored by market and economic conditions. In this respect, legacy literature suggesting that market drives innovation capacity (Azoulay, Ding, and Stuart, 2005)(Azoulay, Ding, and Stuart, 2006) supports Kodama's view. What appears to have occurred is that Japan's behavior changes are not registering discretely in this data. Japan's new law certainly brings a culture whereby, as mentioned above, Japan's academics enjoyed very collegial relations with industry research associates, into the light. America's academics are latecomers to this level of collegiality, but in both Japan and the US it is now legally above the board, not under the table. Thus, Japan's academics appear to have already resided where US academia has only recently ventured: the triple helix of industry-academia-government cooperation. Descriptive data presented herein provides some credence for this view, but, perversely, contradicts the aim of Japan's Bayh-Dole type law. Prior to the law coming into effect, several patents had academic assignees. Afterward, only one had a public assignee, and that was a hospital, not a university. This happened despite other factors in the cases after the 1999-2004 divide rising slightly. The numbers of cases are too small to create confident statistical analysis,

but the implication is clear and somewhat substantiated by the data. Japan already arrived at America's inventive behavior before it enacted the Industrial Revitalization Law.
Thus, in answering the hypothesis' research question, did Japan's Industrial Revitalization Law change Japan's academics inventive behavior, the answer is that it did not encourage greater participation rates, as it did for America after Bayh-Dole. Further, that Japan's post-Industrial Revitalization Law performance matches America's post-Bayh-Dole, strongly concludes that Japan's law lacked the game-changing incentives underlying America's cultural need for a Bayh-Dole type act.

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Network Indicators of Japan's Academics' Value-adding Practices from their Intellectual Capital:
Insights from Pharmaceutical Industry Commercialization Data

Contents

This dissertation has seven steps. Its introduction surveys how and why academics' intellectual capital is commercialized. Concepts and treatment are given and scope delimited by literature review of law and policy, networks, pharmaceutical innovation, intellectual capital commercialization, and Japan-US comparisons. It guides the hypothesis. From that, the analysis configures the hypothesis-testing statistics. Results explain each statistic. Last, conclusions, interpretations and extrapolations evaluate the statistics. Further research is suggested for unanswered questions. Thus, each of the seven builds toward scoring the performance of Japan's academics' performance commercializing their inventive capabilities. The following table of contents tracks each step by page:

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Appendix

1. Introduction

1.1 Purpose of this Study

This dissertation aims to unbiasedly verify if Japan's academic researchers' style of innovating changed pre- and post-Bayh-Dole using America's experience as a null condition. This is achieved by using only (a) pharmaceuticals (which Japan and the United States share the same markets, generate most TLO/TTO revenue, and are fully, publicly disclosed) (b) innovations' (all USFDA-CDER approved drugs) (c) inventions' inventors (drugs' USPTO patents' date and patentee and assignee nationality) by (d) their academics' proprietary contributions during invention (patentees' affiliations—academic or not). Thus, discerning if Japan's and America's academics' innovation evolved assesses affiliations among pharmaceutical innovations' co-patentees prior to and during the Bayh-Dole era.

1.2 Structure of this Introductory Chapter

After the purpose outlined above, this introduction frames the study of innovation and this dissertation's placement within and contribution to it. Its theory, terms, and context of study of technology innovation are this introduction's next three sections. The focus and significance of this dissertation follow them. Finally, this introduction transitions to the next chapter, which shows legacy literature that led to this dissertation.

1.3 Theoretical Framework of this Study

Fail fast. Speed is success in innovation, so underpins this research. While most innovation network research tallies geography or patent citations, these say little about academics' value-adding

practice. Herein, speed of academics selling their intellectual property rights is identified by the composition of innovations' patents' co-patentees. Their networking for speed is a value-adding practice. Speed and value adding theory is stated below.

Academic proportion among co-patentees shows speed. Since universities do not retail drugs, their knowhow and inventive seeds are transferred to firms that develop, market, and sell them. Pharma firms are time sensitive. Thus, early transfer of academics' IP-rights has firms add their researchers to complete the inventions. More academics shows IP was retained longer, fewer shorter.

Academics' speed adds value differently than commercial researchers'. Logically, more research reduces risk. Reduced risk improves a seed's value by reducing its chance of failure. Thus, it adds value for academics that retain seeds longer.

Additionally, to achieve the highest order of unbiased appraisal, analysis depends on data provided without reference to this study. It uses no questionnaires, interviews, case studies or other ways to access the data in which any interaction between the dissertation's researcher or hypothesis could potentially impose any parallelization or selection bias. Though much legacy literature is quantitative in the sense that it uses quantitative assessment methods, this study's dependence on source material where reporting was done for other purposes makes it more than double-blind. USFDA-CDER approvals reports are motivated by interest in US commercialization. USPTO patent data is reported as part of the knowledge dissemination for monopoly protection contract that

a patent provides. Journal and professional publications are used for academic and professional purposes. None of these reports agents or participants have ever been directly or indirectly contacted by any element of this dissertation's research and so cannot have been influenced by it in any conceivable way. This distinction between the qualitative and quantitative are critical to understanding the novelty of this dissertation's research in its fullest.

Thus, this research uses a network analysis framework to compare the evolving ratio of academics among pharmaceutical innovations' inventors as Japan and America imposed similar disruptive policies—each country's Bayh-Dole type law.

1.4 Context of this Study

Innovation has been richly examined, yet several contextual factors beckon new scholarship. Japan's Bayh-Dole system has matured after a shaky start, so longitudinal comparison to America's is timely. Macro-economic analysis of innovations, as opposed to inventions, remains opaque. And, previously used measurement tools have distorted results. Scholarly research tends to suggest divergence between Japan and the US, with Japan underperforming, so Japan's policy results are in question. Thus, a timely, pertinent, and authentic academically rigorous re-appraisal is valuable.

1.5 Focus of this Dissertation Research

This dissertation researches the nature and extent to which policy changes influence the speed of technology transfer among academics who invent for innovated products. Results aggregate innovations' inventors' micro-economic practices, specifically how long before patenting do

academic researchers accept transfer of their ideas to commercializing firms, to determine macro-economic trends arising from policy. Economic theory proscribes that scholarly researchers time sale of their inventions to optimize their reward for risk. Japanese and American cases are derived only from USFDA approved drugs and USPTO patents, to ensure same-to-same comparison, and pharmaceuticals, because its documentation is transparent and as they generate most of universities' IP/IC revenue (Abrams *et al*, 2009). Also, the whole population of approved drugs with patents identified is available. Thus, its focus is restricted to comparing policies' trends in academic researchers' drug industry intellectual capital commercialization.

1.6 Significance of this Research

This dissertation adds to legacy literature in two ways. First, it answers how Japan's academic researchers are accommodating the incentives afforded by new technology transfer policies. Second, it offers new means including: (a) a novel analytical framework, (b) new data source that is a population—not a sample, (c) human choices to measure network analysis of innovation, and (d) linkage of macro-economic interpretations to their micro-economic sources. Therefore, both real world and scholarly benefits accrue.

2 Review of Legacy Literatures

2.1 Introduction

The architecture of this dissertation finds support and references in four literatures. They include: (a) law and policy, (b) networks, (c) pharmaceutical innovation, and (d) intellectual capital commercialization. The purpose of this literature review is to reference how their contents support and limitations produce this dissertation's hypothesis.

An originating axis from which this research emerges is innovation law and policy as when new policy results in a new industry being formed. Patent law, its international treaties and bureaucratic efforts to macro-economically manage inventive and innovative productivity, is one example. Prior to legal recognition of patents, intellectual property contract infringement was largely unenforceable, so its markets failed. Also, before Bayh-Dole act type legislation created a formidable technology transfer industry, its market had been so poorly defined and, thus, risk so acute, technology transfer offices (TTOs) were uncommon and impoverished. In this respect, the America Invents Act, while consequential, is meant only to align US IP processes with global norms rather than define a new or poorly formed intellectual property market. Japan's privatizing of its National universities expanded its market, but that market was defined five years earlier when Japan's version of Bayh-Dole (actually four laws enacted between 1998 and 2004 (Kneller, 2008) including (a) The 1998 Law to Promote the Transfer of University Technologies (TLO Law), (b) the 1999 Law of

Special Measures to Revive Industry (Japan's main Bayh-Dole-type legislation), (c) The 2000 Law to Strengthen Industrial Technology, and (d) The University Incorporation Law.) was enacted and independent universities undertook its new opportunities. Nevertheless, whether it is market-founding, evolutionary or disruptive change, legal and administrative practice defines one parameter for faculty intellectual capital commercialization.

People, not money or geography, invent, so a patentee or co-patentees' inventive decisions best reflect innovative processes. Inventors' socio-professional practice of grouping themselves seeks to achieve their collective goal. Commercially, that goal creates useful, new tools like new molecular entities (NME), mechanical devices, and techniques. Patents describe occupants of the inventive process, including inventors' and assignees' names, locations, and dates. From patents, only in the case of some university assignees, is designation of patentees' or assignees' industry affiliation (academic or commercial) available. Perhaps this explains why patent analysis of networks typically avoids assessing people's affiliations and instead focuses on geography or timing. However, as academics publish books and articles, individuals' academic versus non-academic workplaces can be confidently determined. Knowing that allows network analysis to differentiate between academic versus commercial co-patentees and assignees and suggest at the process of academic technology transfer.

Study of revenue-generating academic technology transfer benefits from a pharmaceutical industry

focus in two ways. Universities' main technology licensure and paid research come from sales to pharmaceutical industry related firms directly or indirectly through transfers to other schools to build toward their own commercial transfers. Most profitable academic technology transfer offices serve universities that include medical schools (Abrams *et al*, 2009). As such, medicine is the prime candidate for research findings that may help academia. Additionally, pharmaceuticals are highly regulated, so documentation is detailed and public within the otherwise quite secretive world of innovation. All USFDA-CDER approved drugs with patent data have been published, so are available for analysis as a population, not a sample. Thus, approvals provide findings on innovation that are relevant to university revenues and its fulsome, public reportage is reliable as a source to for data mining on innovation.

Intellectual property is a subset of intellectual capital. In patents, IP rights divest to assignees from the named patentees, but patents do not identify patentees' roles or contributions. Among patentees, seeds' original inventors, additional corporate, collaborative, or sponsored researchers, including academics, are indistinguishable in patent data. Thus, not differentiating among types of IC roles makes this dissertation's ability to accurately inform on the impact of policy change.

The gap within law, networks, pharmaceuticals, and IC informs about how innovation policy changes alter pharmaceutical inventor networks. First the US and later Japan instituted a Bayh-Dole type law to promote their country's economic development by building academics'

technology transfer market. How academics responded to this change has almost exclusively focused on analysis by citations and geography, not their co-patenting behavior. While pharmaceuticals and biotechnology are very well represented in legacy literature on the impacts of academic technology transfer, using its USFDA-CDER database to calculate innovators' behavior is absent. Derived from patents, inventors' roles by employment affiliation, either academic or not, illuminates that parameter of the co-patentee group's composition. Thus, the gap studied in this dissertation flows from and extends into the gap beyond each of its four boundary parameters.

In conclusion, legacy literature on (a) law, (b) networks, (c) pharmaceuticals, and (d) intellectual capital surround this dissertation. However, they leave a gap that this dissertation's research question addresses. In that space, inductive network analysis of academics among firms' researchers who are active in invention of pharmaceutical innovations clearly indicates how Japan's national innovation system compares with America's in academic researchers' uptake of opportunities arising from Bayh-Dole policy change. Conclusions suggest that in neither Japan nor America have academic inventors made significantly identifiable changes in innovative practices.

2.2 Law and Policy

2.2.1 Introduction

For this dissertation, law and policy starts testing its research question: how do rule changes evolve innovation practices. The Bayh-Dole Act started a worldwide liberation of academia's intellectual

property and remains the global standard. Japan's assimilation came in stages over five years from April 1, 1999, almost nineteen years after America's. Patent law is an earlier foundation that ongoing local, regional, and national programs and institutions continue to transform. Further, firms' policies and organizational contexts color innovation processes, especially when one organizational structure typifies a nation's approach to creativity, identifying its value, and then commercializing it, which narrow and extend law and policy's effects. It is Japan's and America's legal and policy contexts related to academics' that is viewed here. Legal and administrative practice is a defining parameter about which the following authors have parlayed insights.

2.2.1.1 Bayh-Dole

Understanding Bayh-Dole is needed for understanding this research. The research question of this dissertation compares Japan's and America's academics' adding of value in technology transfer over the course of policy changes and Bayh-Dole is the greatest policy change for academic researchers linking both economies. A short history of each country's development and review of laws are provided. Finally, why, despite the dissimilarities in history and law, Japan's and America's Bayh-Dole apparatuses are uniform.

Bayh-Dole type law aims to enhance economic performance by both direct and indirect means. It does so directly by liberalizing academia's intellectual property technology transfer market and indirectly by incentivizing revenue generation by instituting a commercial market for academics'

intellectual capital. America's Patent and Trademark Act Amendments of 1980, Bayh-Dole's formal name, was co-sponsored by Birch Bayh and Bob Dole. It was named "Innovation's Golden Goose" (Economist, 2002) and has been mimicked among most economies with large public funding of academia, Japan included. The Act and its doppelgangers convey ownership of federally funded IP to their universities to optimize the transfer of technology through commercialization.

2.2.1.2 Bayh-Dole's US and Japan Histories

Before Bayh-Dole, two legal models were prominent. One mode had IP ownership principally held by the funding body, so government departments and agencies that funded academic research retained all intellectual property rights no differently than private firms that sponsored research. That was the norm in the United States. Japan followed a model akin to professors' privilege wherein, government sponsored research saw the academic researchers retain control. With Bayh-Dole in the US and the Industrial Revitalization Special Law in Japan, both countries embarked on converging legal trajectories of IP and IC commercialization.

Historically, "total war", especially in World War II, mobilized technological innovations. Countries entered the conflict with systems only a generation beyond those of the war 21 years earlier, but exited it with scientific management, jet aircraft, radar (even air-mobile radar) and counter-radar systems, wire guided munitions and radio-controlled drones, night-vision, and atomic power. At war's end, the systems for government sponsored war effort were harnessed for

reconstruction and economic advantage.

Divergent accountability for scholars' government funded research arose, but, over time, convergent trade standards and comparable developmental goals brought the patterns together again. Japan's post-war government-sponsored research integrated with industry to help it "catch up" with other developed economies in such an orderly effort that it created the "Japan Inc" of the country's heyday. In Japan, fights over IP ownership lacked traction so long as academic researchers leveraged it for scholarly, not commercial, gain and the IP's benefits served firms that, ultimately, served Japan's greater goal of economic progress (Kneller, 2010). A *de facto* "professor's privilege" culture resulted from government's benign neglect of its unexercised IP rights. In the US, government agencies, like NASA, the Department of Defense, and the National Institutes of Health included research budgets from which academic researchers made funding requests. Funding contracts stipulated that intellectual property from that research project belonged to the agency, so maintaining academic independence from commercial interests and lack of favoritism in disposition of tax funded research results (Mowery, 2005)(Azoulay, January 2006). Thus, litigious, contract-based America's Ivory Tower culture disenfranchised academic inventors while Japan's Ivory Tower leveraged IP to enhance their career research, students, and relationships.

Later, comparable developmental goals brought Japan's and America's patterns together from their divergences. Both sought to re-energize economic growth through innovation. Secondarily, but

still critically, weaning academics from near complete reliance on government for research project funding was sought. These two goals brought Japan and the US to the same legal standard.

In the US, outside government-funded research, universities and their academics generated their own rules and precedents such that several formed technology transfer offices long before Bayh-Dole. The Wisconsin Alumni Research Foundation is one of the oldest and a model for the Bayh-Dole era industry in the US and, so, much of the world. WARF proved more successful in technology transfer than did the entropic system held up within the federally funded research agencies, which led to Bayh-Dole legislation aimed at getting languishing technology "off the shelf" and support dynamic new business sectors at the same time. Thus, small business is specifically named as the prime constituency with economic development and march-in rights specified to reduce recitivism.

Japan's laws responded to other dynamics. Seeing US successful technologies licensed or spun out of universities, Japan's economic liberalization efforts saw a Bayh-Dole change as aiding research funding while also effecting economic development that had long been underperforming in Japan. Technology transfer had not been the problem it was for the US. If anything, Japan's technology transfer proved too liberal. Since Japan's academic researchers retained a veto provision over how their intellectual seeds could be deployed, a provision enforced by Japan's US-overseen post-war constitution and empowered by academic militancy and protests in Japan in the 1960s. Armed with this veto, but constrained against actual deployment of their own intellectual seeds and property,

Japan's academic researchers increasingly used such research seeds to cement relationships with Japan's industry firms and government. Japan's academic researchers' technological seeds did not languish on the shelf, because they quickly flowed into firms, an arrangement that government, with its "Japan Inc." mentality, tacitly encouraged. However, with government budgets under pressure from years of economic stagnation, Japan's government entered into liberalization, including its own Bayh-Dole type legislation. Its aim was both economic development and creating an alternative funding source for future research, but moving industry-academia liaison from below to above the table through monetarization of the transaction. Additionally, implementing a US-style Bayh-Dole legal system was seen as better coordinating Japan with global norms.

Therefore, similar aims resulted in quite similar law in Japan and the US. 1970s stagnation in the US and decades of dismal growth before 1990s Japan were confronted with Bayh-Dole type laws. Also, market mechanisms incentivized academics' revenue-generating research. These goals brought both Japan and the US to Bayh-Dole.

2.2.1.3 Legal Provisions

The most important provisions of the Bayh-Dole legislation relating to academic research follow. Foremost, universities and non-profit research institutions, such as federal research institutions and hospitals, may opt to claim patent title for inventions arising from federal government funded research (Mowery, 2005)(Sampat, 2006). Further, university-industry collaboration is encouraged

for the furtherance of research and innovation of inventions such that economic benefits may result (Sampat, 2006)(Kneller, 2010)(Katami, 2011). Meanwhile, the government funding agency retains both right to patent outside of the US and march-in rights to ensure that, if Bayh-Dole subject inventions are mishandled, IP rights revert to it. The Act views universities, research institutes, and hospitals identically and encourages continued academia-industry collaboration beyond just the IP transfer in order to promote product innovations arising from inventions. These two points guide this dissertation's identification of research institutes and hospitals as providing source data indistinguishable from universities and of IC as a fuller proxy for university-industry collaboration than just IP.

Japan's Bayh-Dole type act, the Industrial Revitalization Special Law, taken together with the earlier Patent Law, functions similarly to the US's, though the law confers rights and responsibilities with some nuances. It gave IP title to universities and research institutions, but entered few stipulations on licensure (Katami, 2011). Specific march-in rights stipulate transfer to a third party if the IP is not exploited within a "reasonable period", but that is augmented with government's blanket discretion to usurp IP rights, though no of this action being exercised was found (Katami, 2011). By contrast, Japan's act states no restrictions on universities garnering IP rights or preferences for licensees (not even domestic). It is purely an instrument to revitalize Japan's economy. Operationally, Japan's central government's funding contracts stipulate the terms of IP rights

resulting from the research. These terms are overwhelmingly standardized, but are available for added specification before the funded research is undertaken. Thus, Japan's Industrial Revitalization Special Law and related legislation, though effectively identical in practice, carries a few potentially important distinctions from America's Bayh-Dole.

2.2.1.4 Bayh-Dole's Tactic

The governments of the Japan and the United States of America have made their respective Bayh-Dole type laws and policies important components at the nexus of their support of innovation and universities' funding of their research activities. Essentially, the laws revert commercialization and interest in said commercialization to the institutions that created them rather than in the hands of the funding agency or the privileged professor-inventor. The resultant innovation and subsidization of academics' research are both meant to deliver economic benefits to the institutions and the greater society.

2.2.2 Economic Impacts of Enforcement and Litigation

Two main contributing partnerships comment on the narrow research area of enforcement and litigation and their economic processes for individuals. These are the team of Lanjouw and Lerner, who assess litigation's impact on other propensities within the inventive and innovative processes. Grossman and Lai consider weather harmonization provides incentives or disincentives for invention and innovation. Each team parses application of the laws' economic effects along different axes.

Jean O. Lanjouw and Josh Lerner assess US IP law. Their "The Enforcement of Intellectual Property Rights: A Survey of the Empirical Literature" (Lanjouw and Lerner, December 1997) distills four impacts from IP litigation. First, litigation's anticipated benefits determine its likelihood. Second, its cost diminishes willingness to enforce IP rights. Third, costs, both anticipated and experienced, reduce perceived intellectual property rights (IPR) value. And last, litigation and its costs cause two effects: (1) innovations get administered as legal chores serving future IPR requirements, and (2) they litigation's future costs diminish and innovations in areas where litigation is proven to be less costly and less likely receive more resources. How viable threat of litigation is a tool of pharmaceutical firms to reduce costs of supply of academic researchers' inventive seeds.

Lanjouw and Lerner's findings suggest that pharmaceutical industry capacity to litigate overwhelms academic would-be inventors' compensation demands. USFDA's disclosure requirements raise visibility (reducing IP holder's litigation costs) and punish by obviating costs from infringement (raising IP holders' reward). Subtracting the time of the approval process from patents' life shortens monopoly profit-taking (raising defensive litigation's benefit to IP holder). Universities and academics lack litigation funding (reducing anticipated value of their IP), so academia most benefits from avoiding litigation. Avoidance is achieved by either secrecy, which counter's academics' need to publish, or speedy divestment to pharmaceutical firms, which reduces litigation

risk by transferring under-proven IP seeds to firms. Danger of litigation deflates IPR value. Younger, so riskier, seeds command lower prices. Quick disclosure and licensure of academics' inventive seeds, choosing project consulting, or doing sponsored research diminishes exposure to litigation, but reduces compensation.

"International Protection of Intellectual Property" by Gene M. Grossman and Edwin L.-C. Lai provides the principal dedicated literature for comparative patent law. It tests the relationship between IPR's relative strength in developed countries and shows that patent law strengthens as IP markets expand. Regarding globalization of patent law, they conclude that "harmonization of patent policies is neither necessary nor sufficient for the efficiency of the global patent regime" (Grossman and Lai, 2002). Though their question centers on differences between developed and developing nations, the point is that disequilibria are rational when underlying intellectual capital markets are of different scales (Grossman and Lai, 2002). For Japan and America in the pharmaceutical industry, given that their IP markets fully overlap (all pharmaceuticals IP produced in one will be applied to the other and throughout the world's advanced economies), their market sizes are the same, so the strength of their patent protections will be significantly similar.

In summary, partners Lanjouw and Lerner and partners Grossman and Lai contribute cross-views of economic impacts of enforcement and litigation. The former say that litigation diverts research into less litigious research areas. The latter see harmonization of IP law as detrimental to invention and

innovation. Viewed together, these teams credit enforcement and harmonization as constraints to IP market optimization.

2.2.3 Macroeconomic Effects of Patent Law

Defining patent laws' economic effects, often the motivation for enacting laws, has garnered a range of interest among a variety of authors. Cockburn and Montobbio provide surveys that cover a great deal of the space in this research area.

Iain M. Cockburn's survey "Intellectual Property Rights and Pharmaceuticals: Challenges and Opportunities for Economic Research" (Cockburn, 2009) adds a valuable survey. It identifies gaps in the empirical literature informing IP policy issues. Though mainly concerned with consumer issues, one of its sections focuses on research and development. He cites surveys as far back as 1973 (Taylor and Silberston, 1973) that found pharmaceuticals to be a unique industry for its critical reliance on patent protection, especially as noted by Schankerman (Schankerman, 1998). He states that "research managers typically report that patents are very important to securing competitive advantage, or would reduce R&D by a large fraction (over 50 percent) if patent protection for pharmaceutical products were removed" (Cockburn, 2009). Pharmaceutical R&D expenditures show inconsistent response to changes in patent policy changes. Where Scherer and Weisburst found no effects from improving patent scope, Canada experienced a drop then rise in patenting when compulsory licensing was introduced then repealed (Scherer and Weisburst, 1995). However,

they barely mention academia and never Bayh-Dole. Thus, Cockburn's survey reinforces Grossman and Lai on relating large IP market with strong IP rights, but without stating the significance this has for academics.

Fabio Montobbio's "Intellectual Property Rights and Knowledge Transfer from Public Research to Industry in the US and Europe: Which Lessons for Innovation Systems in Developing Countries?" (Montobbio, 2009) specifically addresses universities. However, by digressing from law and policy to market mechanisms and organizational administration, his report shows that intellectual property rights are the tail that does not wag the dog, but economics of business that does. Further, its avoidance of theoretical models limits the findings' applicability to this research. He notes two contradictory perceptions of universities acting as commercializers of IP following introduction of the Bayh-Dole Act. An Economist editorial presents a positive view when saying:

> Overnight, universities across America became hotbeds of innovation, as entrepreneurial professors took their inventions (and graduate students) off campus to set up companies of their own. (Editorial, The Economist, December 4, 2002)

Whereas, Fortune Magazine counters:

> Universities have evolved from public trusts into something closer to venture capital firms. What used to be a scientific community of free and open debate now often seems like a litigious scrum of data hoarding and suspicion. (The Law of Unintended Consequences—Clifton Leaf—Fortune

Magazine, September 19, 2005)

Montobbio finds in Leaf the anti-commons argument that commercializing university research hinders information flows, so stifles innovation (Montobbio, 2009). The argument is that universities earning rent from their pharmaceutical research encourages hording of the knowledge that creates a bottleneck to dissemination of new technological knowledge in the industry. However, the studies Montobbio surveyed found no strong evidence of anti-commons or foreclosure of public research in fields important to university patenting. Endogenous issues like, as he reports from Stephan *et al* (Stephan *et al*, 2007), (a) context, (b) sponsored research versus consulting (and perhaps versus seeding), (c) university's size, (d) IPR staff's competence, and (e) persistence of academic inventors, all impact on academia's IP productivity. As such, Montobbio finds endogenous factors have a discernible impact on inventions' commercialization whereas the specifics of intellectual property legislation's effects are indeterminate.

Two good surveys seek to ascertain the impact of patent law on economies through support for innovation. Neither finds this result. Instead, both Cockburn and Montobbio determine that institutional, professional, and economic factors drive inventiveness, particularly at universities.

2.2.4 Conclusion

In summary, law and policy provide few restrictions on this dissertation's research into intellectual capital network indicators of speedy innovation processes. Surely, patent law started the IP market.

Surely, Bayh-Dole launched university technology licensing as a working market and industry. Without enforceable intellectual property rights, no value can be generated that is not speculative and not founded on a mechanism like secrecy, trust, or difficulty in reverse engineering products. However, after initiating the markets, it is those market mechanisms and other endogenous factors, not the laws, which drive innovation processes. In that market, academics' compensation is diminished by litigiousness in defense of IPRs and Japan's and America's pharmaceutical IP markets coincide globally, so IPRs are comparably mature. Thus, these law and policy surveys combine broad information to show that IP markets, not laws, are the locus for testing the generation of revenue for academia.

2.3 Academic Social Networks

2.3.1 Introduction

While social network impacts were acknowledged at the outset of scientific management, the Hawthorne studies and writings from Brian Uzzi, such as "Sources of Embeddedness," breathed new life into its study. They and much research that followed seek to understand either what precipitates social network formation, as did the Hawthorne Studies, or, as Uzzi's "Embeddedness," what it produced. This dissertation uses it differently. It examines inventive social networks' (co-patentees') composition by affiliation (proportion of academics) as approximates of innovative processes (speed to sell inventive seeds). Using the proportion of academic co-patentees to explain

the speed to commercialize inventive seeds is a new methodology. Several streams of scholarly thought touch on this, but not explicit protocols for the analytical method applied herein.

Given the range and depth of scholarship on social networks, this list of its top scholars cannot be exhaustive, but it does provide a foundation. With his focus on speed as a consequence of trust within business networks, Bart Nooteboom's scholarship stands out as the main influence on this dissertation's research. Indeed, the analytical methodology mentioned above derives from Nooteboom's research on trust-speed relationships with suppliers. Jason Owen-Smith, Walter W. Powell, and Pierre Azoulay specify how networking impacts on innovation. Powell also contributes with a focus on the pharmaceuticals industry as does Patricia Dajou. Comparison between Western or American versus Japanese social networks is provided by Lynn G. Zucker and Michael Darby, Fumio Kodama, and Ikujiro Nonaka. Authors in each of these three areas are summarized below.

2.3.2 Networks and Innovation Speed and Cognition (Nooteboom)

Bart Nooteboom's work assesses industrial linkages for innovation. As mentioned previously, Nooteboom's view of networks as producing speedy innovation insinuates this dissertation's analysis, which simply reverses his direction of causation. Instead of linkages (networks) being causal, this dissertation tracks innovative speed as reflecting (as parallel or proxy) the composition of co-patentees' affiliations. Broadly, his innovation research evolved from a general transaction-cost

analysis to a more focused look at inter-firm linkages, and finally, presently, to the cognitive underpinnings of choices. It is a stark macro-to-microeconomic arc of career research. This dissertation, though, borrows mainly from his focus on networking for speedy innovation in his mid-career efforts.

Two main Nooteboom texts informing this thesis include one about inter-firm goals, and a second about innovators' cognition: embodied cognition and cognitive distance. In "The Changing Boundaries of the Firm: Explaining Evolving Inter-firm Relations," (Nooteboom, 1998) cost, quality and learning-based governance of transactions are product innovations' function and trust is its dynamic. Network relationships that lower costs, raise quality, or add learning benefit firms enough to risk teaming up. Five competing approaches to inter-firm collusion are (a) the Fordist world, (b) the Japanese world #1, (c) the Japanese world #2, (d) world of the clan, and, (e) raplex world (Nooteboom, 1998). "A Cognitive Theory of the Firm: Learning, Governance and Dynamic Capabilities" (Nooteboom, 2005) explains how firms' function is to align its affiliate's patterns of thought. Its chapter Organization between organizations employs embodied cognition and organizational focus to explain (a) boundaries of the firm, (b) cognitive distance, (c) complications (of cognitive distance), (d) inter-organizational collaboration, and (e) networks. Dr. Bart Nooteboom's frameworks inform this dissertation's comparisons across Japan's and America's national innovation systems with a focus on the role of university IP commercialization using

medical technology data—innovation, learning, alliances, and networks are all present.

2.3.3 Networks and Valuation (Hall and Azoulay)

Bronwyn Hall and Pierre Azoulay show how to measure value using networks.

Hall outlines networking with Albert N. Link and John T. Scott in 2000's "Universities as Research Partners" (Hall, Link and Scott, 2000). Therein, university-industry partnerships in the U.S.'s Advanced Technology Program suggest academics contribute basic science seeds that progress slowly, but endure. Likewise, Azoulay, with Waverly Ding and Toby Stuart, convey motivators of patenting as social, opportunities for publishing, and earnings. "The Determinants of Faculty Patenting Behavior: Demographics or Opportunities" (Azoulay, Ding and Stuart, May 2005) and "The Impact of Academic Patenting on the Rate, Quality, and Direction of (Public) Research" (Azoulay, Ding and Stuart, January 2006) are tandem articles by the three. The first observed that patenting is a function of scientific opportunities as fully as history of patenting and publishing. Meanwhile, the second found no change in the quality or quantity of academic research from commercialization, but some shift toward commercial subjects.

For this research, these confirm two points. First, that commercial work results in a shift in focus of intellectual capital, though this could be efficiently *ex-post* or anticipatively *ex-ante*. Second, academics compete with firms' internal researchers on knowledge production, with academics, since they are external to the firms, being at a disadvantage and discount. Thus, academics contribute

differently from commercial researchers, particularly adding long-horizon inventive results that are remunerated at a discount while academic research continues at an unchanged rate and quality.

In practice, results are found to agree with the conclusions of Montobbio's survey. "Social Influence Given (Partially) Deliberate Matching: Career Imprints in the Creation of Academic Entrepreneurs" (Azoulay, Liu and Stuart, May 27 2009) finds that scientific opportunities increase academic patenting. The above-stated scientific opportunities reflect the endogenous factors Montobbio gleaned principally from Stephen *et al.* It is a product of academic inventors' embeddedness within a network of influences, funding, and professional demand for groundbreaking research. "Acquiring Knowledge Within and Across Firm Boundaries: Evidence from Clinical Development" shows that universities' inventions are afforded higher value and recognition than internally sourced ones (Azoulay, November 2003). Exogenous commercial, institutional, and professional inputs are pre-eminent.

The main concept Hall and Azoulay add is how value is measureable through network analysis. The connection between duration of the inventive process and the presence of academic researchers is assessed as a positive relationship. Additionally, administrative input is part of the inventive process, particularly for academic researchers. As such, these legacy literatures support inclusion of both the duration of the inventive process as related to academics and the inclusion of institutional administrative support into the metrics that this dissertation uses to account for academic innovation.

2.3.4 Networks and Embeddedness (Powell and Owen-Smith)

Walter W. Powell centers several major papers on networks in the research field of organizational sociology, some within the life sciences, but, overarchingly, on institutional networking prevalence, practices and impacts. Notwithstanding "Neither Market nor Hierarchy: Network Forms of Organization" (Powell, 1990), network forms of organization with reciprocal patterns of communication and exchange are alternatives to hierarchically or market based governance structures; they are more suited to describing companies involved in an intricate latticework of collaborative ventures with other firms over long periods.

Powell's "Network Dynamics and Field Evolution: The Growth of Inter-organizational Collaboration in the Life Sciences" with Douglas R. White, Kenneth Koput and Jason Owen-Smith (Powell, White, Koput and Owen-Smith, 2005) and "Technological Change and the Locus of Innovation: Networks of Learning in Biotechnology" with Kenneth Koput and Laurel Smith-Doerr (Powell, Koput and Smith-Doerr, 1996) enter into this research. Other informative work in which Powell participated include: "To Patent or Not: Faculty Decisions and Institutional Success at Technology Transfer" (Powell and Colyvas, 2001), "Roads to Institutionalization: The Remaking of Boundaries between Public and Private Science" with Jeannette A. Colyvas (Powell and Colyvas, 2006), "Networks, Fields and Organization: Micro-dynamics, Scale and Cohesive Embeddings" with Douglas R. White, Jason Owen-Smith and James Moody (Powell, White, Owen-Smith and Moody, 2004). These,

broadly, validate networks as an analytical framework for the dynamics of innovation, particularly within academia and within the life sciences. Further, they reinforce institutions' role as enabler of the commercial research for academia, both organizationally and culturally.

In a highly specific look at networks' role in academic innovation practices, Colyvas and Powell provide "From Vulnerable to Venerated: The Institutionalization of Academic Entrepreneurship in the Life Sciences" (Colyvas and Powell, 2007). It describes, as by case study, the move from disdain for, acceptance of, and spread of entrepreneurship among Stanford University's biomedical scholars. Factors promoting and sustaining its evolution proved to be distinct within the work and research networks, but moved entrepreneurship from being odd to accepted to desirable over thirty years. Where his previous research had provided responses mixing results from questionnaires, interviews, and output data, Colyvas' addition lent both a focus on academic institutions and culture change within a networked academic community.

Overall, Powell and his co-authors suggest that, by assessing networks and evolution together, a new and rich explanation of the nature of the field's structure, which they define as decentralized, results. Further, they note that early networking focus on commercialization gets supplanted by collaborative activities by public researchers, private equity and Small and Medium Enterprises (SMEs).

Patricia M. Danzon, Sean Nicholson, and Nuno Sousa Pereira contribute alliance-based R&D

correlated with probability of successful drug trials. Her "Productivity in Pharmaceutical-Biotechnology R&D: The Role of Experience and Alliances" (Danzon, Nicholson, and Sousa Pereira, April 2003) is critical. It confirms that large firm licensees improve late-stage trials' success rates for drugs developed in alliances and finds diseconomies of scope as focused experience begets more successes. For networks and valuation in this dissertation, their findings convey that academics abet both narrow experience's and alliance's positive and significant value for drugs' passing late-stage trials, thereby reducing risk and raising returns' value.

2.3.5 Japan's Nuances (Kodama, Branscomb, Takeuchi, Nonaka)

Japan's experience influenced a group of academics to see networks from perspectives nuanced differently from solely Western scholars. Some are Japanese, some not. This does not suggest that all have like views. Kodama, Branscomb, and Florida address knowledge flows while Nonaka and Takeuchi question hierarchical linkages. The result is analyses along two contrasting axes.

Fumio Kodama's main source has been Japan's high-technology physical science innovations and commercial and manufacturing sectors for his blend of econometric and management analysis, largely featuring the qualitative, comparative analysis of questionnaires to delve into why decisions are made the ways that they are in Japan and the world. He models Japan's research and development to show that its success is pragmatic, not proscriptive. In "Industrializing Knowledge: University-Industry Linkages in Japan and the United States" (Kodama, Branscomb and Florida, 1999) with Lewis

Branscomb and Richard Florida, using history, sociology, and industry perspectives, they discuss how functioning and policy dynamics address the countries' needs. They find that personal university-industry colleaguality is as pervasive in Japan as in the US. Also, universities' basic research, not government subsidies, puts them at the forefront of technological innovation. Last, where nearby communities lack capability to accommodate universities' research-generated advances, the schools can only effect superficial improvements. These findings align Japan's and America's results. In "Emerging Patterns of Innovation: Sources of Japan's Technological Edge" (Kodama, 1995), he outlines how demand articulation and technology fusion, which fit the Japanese management style well, are the source of Japan's R&D success. In "Japanese Innovation Strategy: Technical Support for Business Visions," (Branscomb and Kodama, 1999) the authors found that management practices for science and engineering produce the changes that are the source of Japan and US high-technology innovation. Thus, people drive linkages across institutional divides, while their benefits and constraints appear to arise organically.

Takeuchi and Nonaka concert Japan's organizational management as sourced from the middle and flowing up and down. Most famously in "The New New Product Development Game" (Takeuchi and Nonaka, 1986), Hirotaka Takeuchi and Ikujiro Nonaka, and later Nonaka alone in "A Dynamic Theory of Organizational Knowledge Creation" (Nonaka, February 1994) and with Ryoko Toyama in "The Knowledge-Creating Theory Revisited: Knowledge Creation as a Synthesizing Process"

(Nonaka and Toyama, July 2003) explain that the perspective of middle managers is strongest within firms for knowledge creation. They are at the nexus of fiscal accountability, which is pervasive in upper management, and technological and process capabilities, which occur in production and distribution. As such, middle management is where product, process, and management evolution is most dynamic. "A Theory of Organizational Knowledge Creation: Understanding the Dynamic Process of Creating Knowledge" (Nonaka, Toyama and Byosiere, 2003) Nonaka, Toyama and Philippe Byosiere define a four-stage process mating tacit and explicit knowledge. Its new product development lifecycle is Socialization → Externalization → Combination → Internalization. Nonaka's last work mentioned herein modifies that basic perspective by showing that knowledge flows result in a more nuanced synthesizing or co-creating effect that promotes buy-in, enthusiasm, and collective effort.

Japan's strengths in knowledge creation are an alternate source of success for Westerners. Scholarship on these differences includes two excellent sources, one group centered on Fumio Kodama and another on Hirotaka Takeuchi and Ikujiro Nonaka. Both address innovation and knowledge creation using networks to help explain their findings. Those results suggest that integration and synthesis of perspectives aids both management and product innovation.

2.3.6 Conclusion

Patents' name inventors in networks well. As this dissertation addresses intellectual property from the standpoint of its human inputs and, as shown by the networking of patents' documented inventors and, given their legal status on said documents, patents' legal certainty provides authenticity in its not being a response to direct research questions, but is up to the standards of legal safeguards in one of the world's most legalistic countries—the United States of America. For this report, then, membership in a network of patent inventors informs this research of the central point of their participation. Subsequent elements of their professional and national affiliations tell of the nature of their personal contribution to the group of inventors, from which this report ascribes meaning, and that adds to the overall definition ascribed to their national innovation system.

Thus, non-geographic networks studies check inter-firm or patent-publication linkages, but this social networks study uses co-patentees' work affiliations to indicate speed in the innovation process out of universities. It is an analysis outside the common ways to tap networks, but part of their lessons also pertains to it. From Nooteboom, trust networks speed innovation processes. From Hall *et al* and Azoulay *et al*, networks measure value. From Powell *et al*, R&D networking evolves from a commercialization focus toward collaborative research, a university forte, so breadth of academic co-patentee representation increases, and, from Danzon, diverse academics among co-patentees raises IP value by reducing late-stage trial failures, so depth of academic co-patentee

representation increases. Thus, that speed to academics' transfer of technology ideas to commercial pharmaceutical firms, one part of the innovation process, is testable, that it relates to valuation, and that the breadth and depth of academic participation can be expected to grow all come from legacy literature on networks in innovation, though it offers only weak guidance on network-speed analytical protocols.

2.4 Pharmaceutical Innovation

2.4.1 Introduction

Earnings and data's reliability make examining pharmaceutical innovation optimal. US regulation demands detailed public disclosure in patents (USPTO) and drugs' approvals (USFDA-CDER) and those data-sources are reputable and drugs represented therein are consistent to US law. Also, the size of the US drug therapies' markets demands participation by all drugs able to do so, so data is comprehensive despite drugs' origins. Such documentation and potential revenue attracts plenty of economic policy and managerial science research, of which this dissertation is one example.

The dissertation examines value-adding practices from intellectual capital, which narrows what legacy literature applies to it. Herein, prior works providing background on and validation from mechanisms, motivations, and historical patterns academia-industry cooperation in innovation are included. Niches other than those of direct relevance to the undertaking herein, which is to use pharmaceutical data to track national innovation systems' performance at innovation before and after

policy change, are excluded. Thus, only enough information is provided as gives an overview and notes the peculiarities of the industry relating to its overlap with university academics' innovation commercialization.

Key aspects of pharmaceutical innovation related to this dissertation include several themes. Michie I. Hunt offers an overview of its evolution from which the period and players relevant to this research are gleaned. Dr. Hunt is a practicing consultant. More academic content focuses on specific latitudes within academic's production of drugs' intellectual property. Iain M. Cockburn and Rebecca M. Henderson are premier contributors who focus on IP rights and Public-Private research interactions. Pierre Azoulay, Bhaven N. Sampat, and Frank R. Lichtenberg co-author and they and several less well-known researchers focus on incentives for producing IP. A further diverse group examines market effects for technology transfer and licensing and also academic entrepreneurship on IP production. Again, just material related to academic IP production is included herein. Thus, the following passages discuss each of these three foci.

2.4.2 Innovations' Flat Macro-character (Hunt)

"Changing Patterns of Pharmaceutical Innovation" (Hunt, 2002) by Michie I. Hunt, reviews the Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984's support of generic drugs. Effects proved macro-economic: (a) generic drugs' market share grew and (b) branded drugs' patent monopolies lengthened from incremental innovations. After Hatch-Waxman,

incrementalism became the norm in monopoly rent seeking management of drug innovations. "Incrementalism" is where innovations are added during drugs' prior IP horizon from which, Hunt critiques, benefits are medically insignificant, but do act to extend drugs' monopoly rents by excluding competing generics. Yet, Hunt's market critique validates this dissertation's defining approved drugs as revenue generators, where the qualitative continuum from groundbreaking to monopoly-extending is moot. All generate revenue. Succinctly, Hunt argues that Hatch-Waxman's macro-economic market fails its desired micro-economic ends by increasing monopoly-extending incremental patenting, which shows that incremental as breakthrough innovation behavior are revenue generating instruments alike. Accepting Hunt, this dissertation's analysis sees all patents in its dataset as qualitatively indistinguishable.

2.4.3 Academic Innovation Firm-dependence (Cockburn and Henderson)

Turning to intellectual property rights at the nexus of public and private research, Cockburn and Henderson provide one perspective and Lichtenberg and Sampat another. In "Intellectual Property Rights and Pharmaceuticals: Challenges and Opportunities for Economic Research," (Cockburn, 2009) Iain M. Cockburn outlines where empirical evidence is available and where thin on IPR issues, R&D incentives, and pricing of and access to drugs. However, as this dissertation only gleans information on drug innovation practices, only Cockburn's comment on IPRs role affecting demand through monopoly pricing and supply through property right protections incentivizing R&D adds to

it. He notes that R&D costs rise while, as patents and approval timelines grow, the window of marketable protection shortens, so overall monopoly demand lessens. IC supply is international, but IP demand is a "national patchwork" (Cockburn, 2009). His survey does not address individual inventors' motivations as effectively as it does firms' and no consideration of social networks. However, it discusses barriers and incentives that concur with Grossman and Lai (Grossman and Lai, 2002) in the above section on Law and Policy that comparability of legal markets, both supply and demand, beget comparable outcomes.

With Rebecca M. Henderson, Cockburn counts indicators of pharmaceutical industry innovativeness. "Absorptive Capacity, Coauthoring Behavior, and the Organization of Research in Drug Discovery" (Henderson and Cockburn, 1998) shows that drug firms access external basic research if it fits their absorptive capabilities. Connectivity with public-funded researchers is outward-looking absorptive capacity and forming those connections is firm-dependent. Their "Public-Private Interaction and the Productivity of Pharmaceutical Research" (Henderson and Cockburn, 1997) adds that firms' absorptive capacity correlates with larger R&D budgets. "Balancing Incentives: The Tension between Basic and Applied Research," (Cockburn, Henderson, and Stern, 1999a) with Scott Stern, find that, in Pharmaceuticals, firms' incentive structures render both basic and applied research, but incentives differ—basic earning promotions and applied earning bigger budgets for HR or buying research tools. "The Diffusion of Science Driven Drug Discovery: Organizational Change in

Pharmaceutical Research" (Cockburn, Henderson, and Stern, 1999b) questions the competitive conundrum of why successful practices get adopted slowly. The two factors determining firms' rate of uptake are (a) change is absorbed at varying speeds and (b) starting points vary due to "state dependence", which results from firms' product market position and internal power structure. Best practices in adsorptive capacity and connectivity diffuse at different rates, so explaining how academic researchers feed into commercial research—under firms' initiative, not theirs. Overall, these say that inventions' patentees are composed according to firms' absorptive capacity, which legitimizes using non-academic-to-academic proportion as this dissertation's dependent variable.

2.4.4 Connectivity and Remuneration (Azoulay, Lichtenberg)

Separately, Pierre Azoulay and Frank Lichtenberg anchor a group of co-authors—most importantly Bhaven N. Sampat, in addressing the underlying incentives of drug industry connectivity and impetus for remuneration to public-funded research.

In "The Anatomy of Medical School Patenting," (Azoulay, Michigan, and Sampat, 2007) Azoulay, Ryan Michigan and Sampat examine characteristics of patenting academics. Findings show that likelihood to patent is concentrated among people with greater opportunity for connectivity, such as age, advanced degree, and connected faculty. Azoulay, with Joshua S. Graff Zivin and Gustavo Manso, "Incentives and Creativity: Evidence from the Academic Life Sciences" (Azoulay, Graff Zivin, and Manso, 2011) questions the incentives driving scientific creativity comparing the flexible

Howard Hughes Medical Institute and the punitive National Institute of Health. Findings show HHMI's greater success in producing high-impact articles on topics that are more explorative than their NIH counterparts. Thus, Azoulay-centered research on connectivity and remuneration says that innovativeness resides primarily among researchers who are better connected and administratively supported.

Frank R. Lichtenberg's "Pharmaceutical Innovation, Mortality Reduction and Economic Growth" (Lichtenberg, 1998) performs an econometric investigation of lifetime income. It finds a significant, positive relationship between life, livelihood, and new "priority" drugs. Lifetime income rises from 0.75 to 1 percent annually and the return-on-investment is as much as 1.8. With Joel Waldfogel, "Does Misery Love Company? Evidence from Pharma Markets Before and After the Orphan Drug Act" (Lichtenberg and Waldfogel, 2003) finds that longevity increases correlate with increased use of pharmaceuticals, more for persons with multiple conditions, even more for those with rare conditions, and most for those benefitting from orphan drugs, the latter of which has improved since the passing of the Orphan Drug Act of 1983. Notably, the Act incentivizes drug innovation by cutting taxes. As the rare conditions they treat are obscure, they befit the rigor and social agenda of academia, so are a catalyst for academic-industry cooperation. They increase academic basic research's input precisely because they are low value, long odds projects that benefit from scholars' slow research and access to alternative funding. Finally, he and Bhaven N. Sampat's

"What are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?" (Sampat and Lichtenberg, 2011) uses a patent-sourced sample of data on approved drugs to find that direct government research aid is most important for priority-review drugs versus standard-review ones, its funding having added to half of all approved drugs and two-thirds of priority drugs. Thus, academics' add unique commercial, social, and economic value in drug innovation, particularly in the R&D pipeline for priority and orphan drugs.

These authors' articles show a pharmaceutical industry that is acutely benefitted by government funding for priority drugs. Academics seed these new drugs, be they Orphan or wide-use drugs. What is clear is that governments' flexible funding strategies beget fast failures and long-term successes benefitting patients with compounded ailments and increasing both longevity and work-life to aid economic productivity. As Cockburn *et al*'s body of work shows that a bottleneck exists with firms' limited ability to absorb through open innovation, Azoulay and Lichtenberg's articles show that academia offers no such barrier within the drug pipeline. Thus, firms punish academic suppliers of innovation for those firms' own dysfunctional demand.

2.4.5 Mitigating Factors in the Academic-Industry Nexus (Philipson)

Varied authors provide useful qualifiers for understanding how structures and incentives at the university-industry nexus behave. Some specific numerical relations identify limits to factors named in pharmaceutical innovation sections above. Added to the sections on Innovations' Flat

Mono-character, Connectivity and Remuneration, and Firm-dependence, a fairly nuanced view of academics' relationship with industry becomes clear.

Risk augments downside costs. Joseph H. Golec and John A. Vernon's "Financial Risk in the Biotechnology Industry" (Golec and Vernon, 2007) finds that Biotech's 38 percent ratio of R&D spending to total firm assets versus 3 percent average for all industries shows its relatively high cost of capital at 16.25 percent. Susceptibility to policy shocks produces this high cost of capital. Margaret K. Kyle's "Strategic Responses to Parallel Trade" (Kyle, 2007) shows pharmaceutical firms' earnings sensitivity as, in response to the European Union's revisions to allow parallel trade, such arbitrage threatens pricing flexibility. Parallel trade means that the same products may be imported-exported anywhere within the EU, thereby leveling prices throughout. It threatens profit in richer countries and re-exporting of drugs diminishes poor ones' supply. Rather than pricing equally throughout the EU, pharmaceutical firms jealously defend price differences through non-IP means and subverting the parallel trade legislation. This shows their revenue sensitivity. High cost of capital due to higher risk from policy shocks, long R&D timeframes with short monopoly marketing periods, and the innate risks of failed drugs combine to impinge on academics inventors' remuneration, through the high level of R&D expenditures. Seeds become expensive cost centers, not profit centers. Thus, the pharmaceutical industry's innovation is highly susceptible to policy risks, which affect pricing, so revenue, and cost of investment.

Three articles headlined by Tomas J. Philipson add another dimension relating market-incentives to innovation. With Stephane Mechoulan, "Intellectual Property and External Consumption Effects: Generalizations from Health Care Markets" (Philipson and Mechoulan, 2003) explains how *ex-post* efficiencies generated by Pigouvian incentives competitive externalities fail to accomplish significant changes. Extrapolating from this, incentives impact the innovation phase, not invention, because revelations are not market-based. Their and Anupam Jena's "Health Care, Technological Change, & Altruistic Consumption Externalities" (Philipson, Mechoulan, and Jena, 2006) adds that innovators cannot appropriate altruistic surplus—benefits to society. The inappropriability stems from altruistic benefits being unanticipatable during the R&D phase and invisible to commercial transactions even at the time of the benefits occurring. Finally, Philipson and Eric Sun's "Is the Food and Drug Administration Safe & Effective?" (Philipson and Sun, 2007), which calibrates efficiencies gained sacrificing safety for speed, results in an over 50 percent increase in efficiency, as much as 66 percent of US sales given the improvement of as much as 15 percent from the less complete, but real, Prescription Drug User Fee Acts. Thus, since academic researchers lack direct access to Pigouvian incentives or altruistic surpluses from firms that are also constrained by uneconomical safety approvals over market-based accountability, incentives available to them from firms diminish by more than 50 percent. Thus, Philipson *et al* find that intellectual property transfers efficiencies away from pricing, because of patents' monopoly position, and toward

non-price competition, such as marketing, so reduces macro-economic efficiencies by as much as 15 percent. Given this, the marginal value of monopoly price protection is clear and shows patents' value in price-setting during and after the monopoly is in effect. A portion of that extra value populates the market for new drug inventions and is paid, in part, to academics supplying intellectual capital to the innovation process.

Daron Acemoglu and Joshua Linn's "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry" (Acemoglu and Linn, 2003) fills in another part of the puzzle relating innovations to populations. Measuring market growth demographically, they find that percentage growth of its category results in 4- to 6-fold increases in entry of new drugs. The finding appears robust even accepting endogenous variables. Since this finding includes both generic and new branded drugs, the proportional increase in demand for academics' seeds is imprecise, but clearly present and significant.

New firms add technology transfer option for academics. Andrew A. Toole and Dirk Czarnitzki's "Biomedical Academic Entrepreneurship through SBIR Program" (Toole and Czarnitzki, 2005) finds that entrepreneurship is used by academics as a distribution channel for their inventions. Also, said academic SBIR start-ups perform better than new enterprises outside SBIR. This indicates that drug commercialization is supported outside the "academia-big pharma" nexus, and successfully so. Likewise, academic researchers are able to circumvent the bottleneck that originates with firms'

uptake constraints.

Together, these authors add nuance to the incentives and management characteristics that pull academics to firms that would commercialize their inventive seeds. Principally, the nature and intensity of firms' constrained market demand is expressed. Some push is also seen as academic seeds both overpopulate supply and start-ups are made to bypass firms' demand constraints. Therefore, it is clear that academic researchers do not retard the innovation process below its optimum, but, instead, pharmaceutical firms' rationally limit their exposure to various risks and face: (a) limited funds, (b) compound costs during the R&D process that make it a cost-center, and (c) entrepreneurial path to commercialization to bypass firms' managers' slow uptake of connectivity.

2.4.6 Conclusion

The prior works above provide background on and validation from mechanisms, motivations, and historical patterns academia-industry cooperation in pharmaceutical innovation. Hunt and Cockburn give overviews of the industry, first, of its market and, second, of its academic issues. Cockburn, Henderson and Stern add that academics' involvement in innovation is firm-dependent while a series of articles separately co-authored by Azoulay and Lichtenberg explain that academics' seeds for priority-review drugs offer no barriers, so firms are exploiting their own deficiencies to under-compensate academic researchers. A diverse group of writers show many aspects that explain the broad effects with specificity, including reasons for firms' constraints and ways academic

researchers address those constraints, such as circumventing them through the R&D stage through entrepreneurship. Thus, mechanisms, motivations, and historical patterns of university-industry connections fostering new drugs sees academics finding workable alternatives when confronted with exogenous constraints from firm-based deficiencies.

These nuances add qualitative and some econometric evaluation to support the data-driven analysis presented in this thesis' analysis. Additionally, it is noteworthy that the industry already attracts considerable attention from academics studying implications of policy options on it. USPTO and USFDA-CDER freely offer extensive data that makes it a suitable target for analysis of pharmaceutical innovation and its value to universities is greater than all other industries combined. It was for those reasons that this dissertation's research deems itself pertinent, informative, and valid.

2.5 Academic Intellectual Capital Commercialization

2.5.1 Introduction

While much is written about academics' intellectual capital commercialization in pharmaceutical innovation, some valuable examination of academics' contributions lies outside the sphere of drugs. This section looks at several, especially the blunt criticism that Bayh-Dole fails its intended purposes. As such, legacy literature on academics' intellectual capital commercialization pares off the previous sections' reviews on academia while adding non-pharmaceuticals derived findings. Also, though both share several authors, several additional researchers are included herein that did not qualify

above.

Several co-authorship groups independently address intellectual capital. Bronwyn Hall centers one constituency who typically examine the economics of IP by relating patent data with other quantitative statistics. Marie and Jerry Thursby center a cohort studying innovation qualitatively by emphasizing the views of managers such that their work falls into Business Administration, not Economics. Scott Stern, Michael Porter, and Jeffery Furman address national innovation capacity macro-economically. Iain Cockburn extends beyond his pharmaceutical innovation work into more general conclusions, like offering the Anchor Tenant hypothesis as an alternative analysis to explain clustering effects that are not horizontally agglomerative, but, instead, produce vertical collocation effects. Mowery and Audretsch criticize Bayh-Dole as failing academic entrepreneurship. Plus, numerous additional researchers offer new insights, including some with notoriety, like Trajtenberg and Powell. Compiling this body of legacy literature educated this dissertation both with background and tried analytical options other than that derived from Nooteboom's network methodology.

2.5.2 Introductory Background Information and Reflections

Before discussing articles, these background paragraphs summarize national innovation systems. National innovation systems corral innovation's units of analysis within the regulatory, historical,

cultural, and market in which they operate. An overview of how such systems may be recited and interpreted is suggested in a preliminary fashion below.

For this dissertation, the Organization for Economic Cooperation and Development (OECD) defines them in its 1997 report "National Innovation Systems" (OECD, 1997). It offers six definitions. Herein, the earliest by C. Freeman from his article "Technology and Economic Performance: Lessons from Japan" (Freeman, 1987) is used:

> *"...the network of institutions in the public and private sectors whose activities and interactions initiate, import, modify and diffuse new technologies."*

It works for this report best as it includes networks and is not convoluted. Its weakness, common to all six alternatives, is that it ignores individuals as discrete elements in the innovation process, though, from its introduction, the OECD article outlining NISs starts with people as "(t)he national innovation systems approach stresses that the flows of technology and information among people, enterprises and institutions are key to the innovative process" (OECD, 1997). Further, it links directly with this dissertation in naming "interactions among enterprises, universities and public research institutes, including joint research, co-patenting, co-publications and more informal linkages" (OECD, 1997) as the second of four types of knowledge flows (the fourth being personal mobility). Its definition of "cluster analysis" includes a derivation like this dissertation's use of networks and identifies four types of "indicators", the first two of which, "1) human resource flows; 2) institutional linkages," are aspects that require future research. Essentially, national innovation

systems analysis concerns knowledge flows along institutional and personal linkages just as this dissertation considers them.

Scott Stern, Michael E. Porter, and Jeffrey L. Furman straddle from Hall's research to the Thursby's. Alone, "Do Scientists Pay to Be Scientists?" (Stern, 1999) bolsters the Thursby-Jensen focus on technology transfer mechanics with micro-economic findings. It shows that firms with higher quality researchers allow more basic research, but at an average 25 percent wage discount, so "scientists do indeed pay to be scientists" (Stern, 1999) at least at their initial hire. "The Determinants of National Innovative Capacity" (Furman, Porter, and Stern, 2000) offers this definition:

> *National innovative capacity is the ability of a country to produce and commercialize a flow of innovative technology over the long term.*

Noting that national innovative capacities of OECD countries have been converging since the 1980s, its macroeconomic analysis explains that productivity's flattening throughout the world pushes high-wage economies to depend on high-return innovations in order to compete globally. Innovation "depends on an interaction between private sector strategies and public sector policies and institutions" (Stern, Porter, and Furman, 2000). Their study finds that, despite the differences in economies' inputs for innovation, like R&D staffs and investment, it is research productivity from (a) IP protection, (b) will to trade globally, (c) amount of firm-sponsored academic research and (d) IP licensing from public institutions by firms, that factor most in building technological knowledge stock and commercializing it for value-adding export. Thus, the industry-academia nexus

macro-economically shows benefits to innovation from firms' investments in university research, but without pinpointing either whether or how that investment aids the investing firm since, allowing for spill-over and other diffusions, other outcomes are distinctly possible, and without identifying the locus of value generation as at the university, faculty, or individual researcher level.

Another derivation is to calculate speed of the dissemination of innovation and innovations, again macro-economically. In "The Diffusion of Innovations: A Methodological Reappraisal" (Trajtenberg and Yitzhaki, 1982), Manuel Trajtenberg and Shlomo Yitzhaki convey that logistic distributions undermine comparability and interpretation while also biasing data. Changing to the Gini Index's "expected mean difference" for analyzing speed of diffusion of innovations is demonstrated as more accurate. Therefore, provided that the positive relationship linking commercial dissemination of innovations with the propensity of innovate is affirmed, analysis by mean difference is shown to offer a most accurate representation a national innovation system's processes via their outcomes. This dissertation utilizes difference of means for its analysis.

Mainly, the above information offers working definitions of what national innovation systems are, what they do, and why they are important. Also, an optimal mechanism for analyzing its measures is named. Those definitions and the analysis presented above derive from macroeconomics. The more specialized articles below offer other angles of assessment, including microeconomic.

2.5.3 Academics' Innovation Processes

Herein, broad content on the process of innovation at universities and public research institutions is noted from Burns and Stalker on one hand and Cockburn on the other. Burns and Stalker wrote a seminal early text on innovation management with both networking and pharmaceutical industry examples included. Likewise, Cockburn used network assessment and pharmaceuticals data, but wrote extensively and recently. Though their discussions of intellectual capital commercialization lack the robustness of their main interests, their work still deserves mention here for its foundational content.

"Management of Innovation" (Burns and Stalker, 1994) by Tom Burns and G. M. Stalker is as fully a starting point as that by Schumpeter, Kirzner, or Taylor. It is a powerful formative text upon which the field studying innovation in firms is founded, yet the one word in its title that distinguishes it from other research presented herein is, curiously, "of." It is not some other preposition. From "of," the text examined "organizations under condition of relative stability and change," "the plurality of social systems within the organization," and "organizational dynamics" before proffering the authors' impression of "the new industrialism" (Burns and Stalker, 1994). Had that "of" been a "for", then the text would have meshed with this thesis, which concerns creating innovations, not the ingenuity of organizational systems and societies in accommodating change. "Of" allows that innovation is the As such, "Management of Innovation" offers little but background to this

dissertation except to note firms' tension between navigating change and novelty versus engineering product R&D pipelines that are outside the firm's path dependent scope. The university-industry nexus is often reported to exhibit a clash of cultures, since corporate administrations tend to reinforce efficiencies in core competencies over trailblazing lack of accountability.

Cockburn's work mostly relates to Third World pharmaceuticals and to software. Among Cockburn's bounty, one article provides background as sought in this section. "University Research, Technology Commercialization, and the Anchor Tenant Hypothesis" (Cockburn and Agrawal, 2002), with Ajay Agrawal, adds the Anchor Tenant hypothesis for consideration. Findings postulate that a given anchor tenant's network tends to include only its silo, only its scope, from its suppliers to its distributors, not parallel "tenants" that create economies of scale.

Burns and Stalker and Cockburn add foundational strength. While of limited appeal, their writings did upheld intellectual capital's role more broadly than IP alone. However, their impact herein was largely reduced to background information and one article by Cockburn where the Anchor-Tenant hypothesis probes the nature of the connection of intellectual capital commercialization processes. The specificity of this dissertation draws from them more as background than as direct incisions.

2.5.4 By Financial Measurement

Bronwyn Hall is a heavyweight among innovation scholars and probably its main quantitative analyst as she and others connected with her track innovation's financing. Given the strength of

their scholarship, several of her works influence this research.

Alone, Hall authored six summarized articles. "Measuring the Returns to R&D: The Depreciation Problem" (Hall, 2007) contrasts two methods of assessing R&D depreciation, (a) the production function, and (b) firm market value. She finds that results are wildly divergent and also divergent from the 15 percent rate standard in academic research in assessing depreciation on R&D investment. Firm market value results suggest a 20-40 percent depreciation while the other suggests none. "Is Public R&D a Complement or Substitute for Private R&D?" (Hall, 1999a) Does it add to or crowd out private research and development is the question that her results cannot clearly answer, despite efforts to improve scholarship. She asserts that it is unfinished work still seeking means for clarification. "The Financing of Research and Development" (Hall, 2002) surveys evidence on the R&D funding gap persisting even without exogenous incentives to under-invest. Cost of capital mainly constrains pay for R&D. It is addressed differently depending on firm size. SMEs rely on venture capital, which helps, but is an incomplete answer. Large firms rely on internal financing for R&D's sunk costs. Government subsidization results are unclear, but opacity may come from poor measurement, so requires more study. "Innovation and Diffusion" (Hall, 2005) says micro-economic determinants of the spread of new technologies are economically, socially, and institutionally derived. "Exploring the Patent Explosion" (Hall, 2004) vets information technology and scientific instruments industries' increased patenting (only the latter of which overlaps with

medicine) to find that, since 1984, US patentees have been the main drivers of rising patenting, though Asia added a short term rise in the early period. Additionally, the only point where patenting was shown to add to firms' market value was for new entrant firms developing diversely-and-multiply-patented products after 1984. In terms of firms' market value, patents appear to be defensive tools. "Innovation and Market Value" (Hall, 1999b) precedes "Exploring the Patent Explosion" to explain the underlying theory to show that US firms' knowledge assets relate both strongly and positively to firms' market value, particularly for firms new to markets, and (b) patent measures contain more nuanced information about this valuation than is typically reported. Thus, Hall's articles explain capital and market determine R&D funding, but knowledge assets, not patents, provide reflection in firms' market value, especially for new entrants.

Hall's co-authored articles tend to be more multi-dimensional than those she writes alone. Five such papers benefitted this dissertation. With Paul A. David, "Heart of Darkness: Modeling Public-Private Funding Interactions inside the R&D Black Box" (Hall and David, 2000) explores the sometimes contradictory findings on results from mixing public and private R&D funding. To help make sense despite inconsistencies, they identify the main channels for public R&D and their short- and long-run effects for national innovation systems. "The Market Value of Patents and R&D: Evidence from European Firms" (Hall, Thoma, and Torrisi, 2007) with Grid Thoma and Salvatore Torrisi relates European firms' quality patent and R&D value to stock market valuation. Tobin's q

shows a significant positive association if present in the USPTO, though this appears affected by a "patent portfolio" practice common to software patenting. However, unfortunately, Tobin's q, a stock pricing analytic, is ill-equipped to assess USPTO designated inventors' congregation. Hall and Fumio Hayashi's "Research and Development as an Investment" (Hall and Hayashi, 1989) indicates that shocks to R&D net investment are immediate and triple that of firms' capital stock using data from three large firms' R&D projects. "The NBER Patent Citations Data File: Lessons, Insights and Methodological Tools" (Hall, Jaffe, and Tratjenberg, 2001) by Hall, Adam B. Jaffe and Manuel Tratjenberg describes recent trends for lags, originality and generality, and self-citations in US patenting and citations. Methodologically, they suggest using (a) a fixed-effects approach that scales citations according by technological category and (b) a quasi-structural approach that distinguishes multiple effects on citation rates via econometric estimation. "Universities as Research Partners" (Hall, Link, and Scott, 2000) with Albert N. Link and John T. Scott found that, in public-private partnering, academics' research tended toward basic science and was put into projects that survived longer than those without academic input. Thus, global patenting adds value while shocks to net R&D investments hit fast and hard against project value that can be measured with specific technological category nuances of which basic research projects have the greatest viability and least risk. Also, analytical factors promoted include a structural approach, a fixed-effects approach, Tobin's q, and short- and long-term time effects.

Therefore, Bronwyn Hall's extensive economic data-mining and analyses add much to consider. Her individual writings focus narrowly and aggregately conclude that funding R&D offers elusive value to firms, but questions the real nature of the patent explosion. Her co-authored ones explain how patents add value differently across the spectrum of firms by size, but, macro-economically, find the effect of policy shocks to reduce both output and future resilience while showing that inventions with academic co-inventors prove most resilient in the face of budgetary shocks.

Inserted into the Bronwyn Hall's field of research on patterns of knowledge flows, Michael Roach and Wesley M. Cohen offer a strictly academic focus in "Patent Citations as indicators of Knowledge Flows from Public Research" (Roach and Cohen, 2010). It supports findings that patents' references to scientific publications are meaningful, but also that they suffer from (a) not showing tacit networking effects or (b) not showing unpatented, unreferenced basic science in patents and academics refraining from citing non-academic sources. From survey data, they estimate the understatement of public research's importance at 55 percent, so it stresses that using patent citations is misrepresenting impacts quite significantly in scholarly papers.

In conclusion, Roach and Cohen's findings bolster Hall's *et al* corollary of financials-based analysis offering comparatively accurate measures. However, founding research into human decision-making about prosecution of the innovation process offers a poor and largely extraneous fit versus network analysis. Thus, it is the non-financial elements of Hall's analysis, such as

time-duration for the scope of analysis, and structural and fixed-effects approaches that benefit assessment of this dissertation's source data, which combines drug approval information with inventor identification and invention timing with recognition of workplace affiliation.

2.5.5 Qualitative Measurement

Jerry and Marie Thursby center co-authors who examine innovation from a perspective that is closer to Business Administration than Bronwyn Hall's Economics, but is of similar influence here. The body of their presented works is divided into two subjects. The first focuses on the economics of university technology transfer. The second group questions new licensing laws' impact on faculty scholarship. Of these two, the former pertains to this dissertation most fully.

Reasons given for industry's funding of academic research and reasons why scholars participate in for-profit research are examined by authors centered on Jerry G. and Marie C. Thursby. Their "Are Faculty Critical? Their Role in University-Industry Licensing" (J. Thursby and M. Thursby, 2003) shows that corporate sponsorships of university research occur if firms do not intensely invest in basic research themselves and that licensing flows from strength of personal contacts between firms' researchers and universities' faculty. "Flexibility: A Partial Ordering" (M. Thursby and Kala, 1994) considers economies' adjustment to exogenous shocks. Regarding policy, they find that putting restrictions on factor mobility and on production hampers its resiliency to price, endowment, and technology shocks such that, when they occur, the shocks diminish both the GNP and its resilience to

future shocks. Shocks hurt and risk hurting more in the future. With Emmanuel Dechenaux, "Shirking, Sharing Risk, and Shelving: The Role of University License Contracts" (M. Thursby, J. Thursby, and Dechenaux, 2005) determines that TTO's preference for milestone and annual payments rather than fixed fees and royalties comes from moral hazard, risk sharing, and adverse selection, particularly related to expectation for march-in rights from Bayh-Dole to prevent shelving of inventions. Richard Jensen headlines both Thursbys in "The Disclosure and Licensing of University Inventions" (Jensen, M. Thursby, and J. Thursby, 2003). Its two findings are (a) that TTOs serve both faculty and universities' administrations and this allows faculty to determine when disclosures occur, and (b) quality of seeds disclosed relates inversely to the amount of remuneration the faculty receives. "Proofs and Prototypes for Sale: The Tale of University Licensing" (Jensen and M. Thursby, 1998) identifies a moral hazard that arises because most licensed IP needs further involvement by the academic researcher-inventor. They find that sponsored research for that follow-up work is insufficient to motivate, because it is not tied to R&D progress. Royalties or equity are optimal motivators. Thus, faculty researchers control their work on inventions, but are disincentivized by pay, preferring fixed fees and royalties over common private firms' remuneration. Incentivization of academic research to become more commercial is another area where the Thursbys center study. "Who Is Selling the Ivory Tower? Sources of Growth in University Licensing" (J. Thursby and M. Thursby, 2007) examines Total Factor Productivity growth from 65

universities through innovation processes' stages. Findings show that faculty and schools seek to sell their IP and firms accept buying external R&D, so sales increases are endogenous, not from scholars choosing more commercial research. They and Anne Fuller, in "US Faculty Patenting: Inside and Outside the University" (M. Thursby, J. Thursby, and Fuller, 2007), find that most of the 26 percent of academics' patents assigned only to firms, not their university (a violation of Bayh-Dole) come from academics' consulting activities. With Swasti Gupta-Mukherjee, "Are There Real Effects of Licensing on Academic Research? A Life Cycle View" (M. Thursby, J. Thursby, and Gupta-Mukherjee, 2005) finds that, except for reducing the amount of leisure throughout academics' lifecycle and for where licensing incentives are very high, neither basic research nor publishing suffer with introduction of licensing to academics' workload. In "Patent Licensing and the Research University" (Jensen and M. Thursby, 2004) Richard Jensen and Marie Thursby build a dynamic model of university research using the Principal(university)-Agent(Faculty) framework to test whether financial incentives are ruining scholarship. Unusually, they determine constraints to agency to be endogenous. They find that the endogeneity and that commercial research also benefits future knowledge both show licensing's detriments to scholarly research to be uncertain. Thus, faculty research remains basic, regardless of normal remuneration and endogenous constraints are limited to those sourced from firms or to very high pay.

In conclusion, literature from the community surrounding Marie and Jerry Thursby and Richard Jensen builds a business case similar in conclusions to those of Hall *et al.* Academics' patterns of research find detriment only under extreme overpay, though are motivated to maintain high activity throughout their careers and source more research ideas in the areas that attract funding from firms. Number and quality of publications remains high. Firms are the bottleneck to adding more capacity of inventive seeds from academics, because those firms lack the ability to absorb them and the ongoing relationships with their academic inventors necessary to complete the innovation. Part of the difficulty absorbing them is the moral hazards that they bring with them and that TLOs/TTOs methods for minimizing them, while not atypical as business models, are less common outside of academia. A great deal of interesting nuance to the functioning of faculty is represented in the body of work coming from the Thursby-Jensen academic community.

Where contradictions between groups of authors exist, the findings of researchers who are independent of each contrastive group are useful to judge which appears most valid. Contrasting with the findings of Cockburn and Hall, but in line with conclusions by Jensen and the Thursbys, in "Incentives and Invention in Universities" (Schankerman and Lach, 2003), Mark Schankerman and Saul Lach find that higher royalty pay for academic researcher-inventors confers higher license income, so productivity increases, not decreases, with higher remuneration. From panel data of over 100 firms, these findings controlled for a long list of impeding factors and, though the general

conclusions did not differentiate, specific conclusions explain that the effect is foremost for scholars at private universities. Thus, with results that controlled for factors that undermine other data, they lend weight to the perspective that research results are driven by pay even in academia.

Another set of independent authors addresses the approaches that motivate investment in innovation. In "Patents and R&D as Real Options" with Jason C. Hsu (Schwartz and Hsu, 2003) and "A Model of R&D Valuation and the Design of Research Incentives" (Schwartz, 2003), Eduardo S. Schwartz explains then applies real options to the issue of R&D valuation for pharmaceuticals in particular. Real options account for both shear and incremental up- and downside factors used in R&D project planning, especially regarding the effects of regulation. They determine that pull subsidies, like purchase guarantees, are most effective at encouraging adequate R&D funding for drugs, cost subsidies less effective, and patent-extension to be ineffectual. This supports other Law and Policy and Pharmaceutical Innovation sections' content that pharmaceutical firms are drug innovations' bottleneck.

In conclusion, the Business Administration approach offers relatively qualitative analysis. Jerry and Marie Thursby lead the main group that suggested that commercial funding helps motivate basic research, but follows firms' ongoing relationships with faculty. Two independent groups of researchers confirm and add to this overall view. Thus, Business Administrative science contends, just as has Economics based principally on financial analysis and on network analysis, that academia

substitutes where firms lack the non-financial resources to do basic researchers themselves, though not developing basic research capabilities appears to be influenced by access to available academics from whom research results may be siphoned to the company.

2.5.6 Bayh-Dole Criticism

The nature of scholarly research is to cast a critical eye on qualified truths. Bayh-Dole type legislation has spread beyond the United States throughout many advanced and developing countries in order to enhance what David C. Mowery and David B. Audretsch define as academic entrepreneurship. This academic entrepreneurship logic is defined broadly to include anything inherently commercial related to formerly Ivory Tower academia. Though they mean the same thing, this dissertation uses the term "commercialization" rather than their "academic entrepreneurship" for two reasons. Primarily, network analysis scholars, particularly Nooteboom and Powell, use "commercialization". Secondarily, "academic entrepreneurship" maintains a perspective from academia suggesting that this entrepreneurship is in question, whereas this dissertation accepts commercialization as a given. As a given, this dissertation's concern is how well academia is achieving goals of commercialization rather than whether it should be doing so. Thus, this section utilizes the findings from Mowery, Audretsch and others without accommodating their analytical predisposition questioning its validity.

For more than ten years, a major component of David Mowery's scholarship has tested Bayh-Dole policies' effectiveness and impact on academic research. These have been both quantitative and qualitative assessments. In "The Bayh-Dole Act and High-Technology Entrepreneurship in U.S. Universities: Chicken, Egg, or Something Else?" (Mowery, 2005), Mowery criticizes Bayh-Dole's perceived importance to certain types of business start-up activity as misguided. He states, "Although it seems clear that the criticism of high-technology startups that was widespread during the period of pessimism over US competitiveness was overstated, the recent focus on patenting and licensing as the essential ingredient in university–industry collaboration and knowledge transfer may be no less exaggerated. The emphasis on the Bayh–Dole Act as a catalyst to these interactions also seems somewhat misplaced" (Mowery, 2005, pgs 40-41). His criticism is not with the law, per se, but with the perceived impact. Instead, he notes that overall trends in the commercialization of academic research was already growing more commonplace and efficient (Mowery, 2005), thereby suggesting that the new law piggy-backed on an already growing pattern. Further, the meager quantitative data that could be mustered on this then new research area found that there was insufficient data to definitively say that Bayh-Dole had caused any meaningful deviation from that trend. Fundamentally, Mowery identifies problems arising from a dysfunctional principal-agent relationship as the source of Bayh-Dole's inability to achieve its objectives. Thus, in that article and several others, including "Patenting and Licensing University Inventions: Lessons from the

History of the Research Corporation" (Mowery and Sampat, 2001) and the book "Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act" (Mowery *et al.*, 2004), the lack of evidence supporting the notion that the Act changed the already upward trend is redacted.

Bhaven N. Sampat continues as Mowery in framing the failure of Bayh-Dole to achieve private and public goals as extensions of the micro-economic Principal-Agent failure. In "Patenting and US Academic Research in the 20th Century: The World Before and After Bayh-Dole" (Sampat, 2006), he concludes that embedding the decision to license or not in TTOs undermines both the free flow of ideas, as per academic independence, in the hope of potentially gaining licensees and also effective commercialization, due to overburdens of non-exclusivity and helping small business. It is noted, though, that Japan lacks these two burdens in its Industrial Revitalization Law, so should produce more free-market results. Thus, by Sampat's stipulation, Japan should outperform the United States.

David B. Audretsch and his frequent co-author Taylor Aldridge's findings coincide with Mowery's, though their more quantitative examination of results that derive largely from surveys and data from the National Institutes of Health enhance those conclusions validity. Their findings in "Does Policy Influence the Commercialization Route? Evidence from National Institutes of Health Funded Scientists" (Aldridge and Audretsch, 2010) notes that the researchers' chosen channel for

commercialization determines whether or not they assign to the university and then license or they start a business for themselves. In this respect, they find that Bayh-Dole was sidelined in the face of the researchers' pre-existing preferences and, so, irrelevant. In "Entrepreneurship Capital and Economic Growth" (Audretsch, 2007), he discerns that spillovers, which exist free of licensing and, so, Bayh-Dole, play the premiere role in affording academic start-ups their growth potential. Audretsch's findings suggest, as do Mowery's, that the problem of a disjunction in the principal-agent relationship is responsible for Bayh-Dole's poor showing.

Finally, Martin Kenney and Donald Patton concertedly argue in "Reconsidering the Bayh-Dole Act and the Current University Invention Ownership Model" (Kenney and Patton, 2009) that under its administration, neither public interest nor private value can be optimized. They provide compelling evidence that the Bayh-Dole system is marred by "ineffective incentives, information asymmetries, and contradictory motivations for the universities, inventors, potential licensees, and university technology licensing offices (TLOs)" that create such structural uncertainties as raise risks for investors and inhibit dissemination of information (Kenney and Patton, 2009). They present alternative structural models for improving either the public good or private enterprise, suggesting that dissemination of research by academics cannot serve both masters.

In conclusion, criticism of Bayh-Dole type technology transfer typically follows two themes. One suggests that it fails at commercialization. The other, effectively, is that in the effort to succeed at

commercialization, it undermines academia's intended free flow of ideas and information. Either explicitly, as with studies from Mowery and Sampat, and from Audretsch, or implicitly, as herein noted from Kenney and Patton, the Principal-Agent relationship appears to be the source of this disjunction. Mowery and Sampat develop results based principally on quantitative assessment of inventor-entrepreneurship. Audretsch and Aldridge mostly use surveys. While Patton and Kenney mix surveys with derivative examination of the administrative systems that result from Bayh-Dole. Overall, Bayh-Dole is found to create structural flaws in administration and service of the commercial market and the social mandate of funding authorities.

2.5.7 Conclusion

Therefore, though a great deal of literature has been dedicated to the topic of academics' intellectual capital commercialization, separate from pharmaceutical innovation and excluding those lacking comment on academics, the above is an informative cross-section. Bronwyn Hall, Marie Thursby, Jerry Thursby, Richard Jensen, Iain Cockburn, Rebecca Henderson, Scott Stern, Michael E. Porter, and Jeffrey L. Furman, and Trajtenberg are high profile scholars in this review. Together, they cover a wide deportment of discourse and analysis of intellectual capital commercialization from both economics and management, qualitative and quantitative, traditions.

2.6 Conclusion of Legacy Literature Review

While Bayh-Dole unleashed universities' to own and contract out intellectual capital under their employ, the above authors show some of the scholarly interest that it has gathered in efforts to settle controversies about its impacts and efficacies. In this dissertation, only parts of this large and varied literature that precisely inform on questions of motivations and structures that alter the interest in and progress of universities' inventions being commercialized are included.

3 Hypothesis

3.1 Introduction

Does co-patentee networks' composition indicate that Japan's academics' practice of transferring intellectual capital to drug commercializers was changed by Bayh-Dole? Most reviewed legacy literature says that whatever changes occurred, the impact continues to lag when compared to US results. However, another line of criticism says that America's results show change that is either insignificant or non-existent. In this respect, Japan's results can be said to converge with US results if both show that Bayh-Dole type law and policy have failed to change the network dynamics in each country.

3.2 Network Logic of the Hypothesis' Argument

Bayh-Dole's purpose was to create market drivers for academia's technology transfer so it would more readily sell its intellectual seeds, invent more, and research topics with commercial potential.

As those market mechanisms reward academics' R&D progress through the innovation process, logically, increasing innovation's reward would increase the threshold for research input to optimize that reward, since other factors, most importantly risks, remain constant. Keeping research longer accomplishes two outcomes. First, commercial researchers' work and earnings are supplanted by academics' (Kenney and Patton, 2009). Second, by extending their research, academic researchers bear more risk of a project's failure (Kodama, 1999)(Kenney and Patton, 2009). Risk devalues technology, so, at transfer, proven research adds value (Kenney and Patton, 2009). Thus, longer research by academics, invoked by Bayh-Dole's market, shows itself in the data as increased proportion of academic co-patentees.

3.3 Novel Attributes of this Research

Two novelties separate this dissertation, Network Indicators of Japan's Academics' Value-adding Practices from their Intellectual Capital: Insights from Pharmaceutical Industry Commercialization Data, from legacy literature. One is the methodology stated in the title: "network indicators of Japan's academics' value-adding practices from their intellectual capital. The other is sources invoked there: pharmaceutical industry commercialization data. Thus, a new perspective derives from the novelty of the source data and the proportions-by-affiliation analytical methodology employed to answer whether Bayh-Dole effected change. The following paragraphs delve into each to clarify the approach.

"Network indicators of Japan's academics value-adding practices from their intellectual capital" is the research question's root. Networks test each patentee's affiliation-differentiated connection with co-patentees—academic or not. The academic composition of each co-patentee network indicates underlying value-adding practices by the academic constituents during projects' R&D process, since their participation is determined to displace commercial researchers (Kenney and Patton, 2009). Proportionately more academics shows that they use more of their intellectual capital, do more research, exert more control in the inventive process, assume more of the risk of failure, and, potentially, earn more revenue and income. Since it measures potential, not actual, revenue, this methodology concludes on innovative capacity (Furman, Porter, and Stern, September 2000)(OECD, 1997), which is a macro-expression of value-adding. Thus, the root question is answered across its micro and macro levels in a method that derives from legacy literature, but, by the streams' integration, boasts novel analysis.

"Insights from pharmaceutical industry commercialization data" narrows and deepens inputs. Scope narrows to just pharmaceutical industry innovation as shown by drug approvals from the United States Food and Drug Administration Center for Drug Evaluation and Research Orange Book of Approved Drug Products with Therapeutic Equivalency Evaluations, from which innovators' characteristics are available (USFDA, 1984-2012). Approval permits products' commercial sale, so, by definition (OECD, 1997), approval raises inventions to innovations, yet USFDA-CDER approval

is nearly unused to assess innovation practices. Only one academic paper, "The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs" by Robert Kneller (Kneller, 2010), used it, though, therein, its use was not central to the analysis. Scale deepens by being a longitudinal, full population of observations, including ample observations from both years before and after each of Japan and the US implemented Bayh-Dole. The data encompasses a population, not sample, including all approved drugs from 1984, when drugs' patents began being published, to when data collection for this research ended in 2012. Analysis occurs at the patent level due to that being the level attributed by legacy literature, particularly that centering on David Mowery (Mowery, 2005). United States Patent and Trademark Office data rules name only inventors, not introducers of new technologies, as other countries' patent rules allow. As such, these sources provide valuable new scope and scale of assessment.

These two novel attributes, source data and methodology, add to research on innovation. They add a new method to assess academics' evolving role in the innovation process, narrow its scope to drugs and deepen its scale with a longitudinal, population of data. They show potential, not actual, financial outcomes via innovation capacity, since statistical results from USFDA source data show innovation inputs, not outputs. If Japan and America's network results compare, but finances contrast, then the incongruence results from the marketplace, not the innovation. Since markets lie outside the scope of innovative capacity, this dissertation does not address any innovation-revenue

incongruency's cause. Thus, this hypothesis tests if Japan's academics' pharmaceutical industry potential to maximize income from the innovation process converges or diverges well or poorly compared to the America's.

3.4 Augmentations of the Data

Two additions augment the analysis that tests this co-patentee-focused hypothesis, impact of the assignee being academic and of number of co-patentees. That a relationship would exist between the number and proportion academic researchers among co-patentees and presence of an academic assignee has been indicated previously (Mowery, 2010). Logically, employees and their employers should be expected to coincide. Also, logically, more co-patentees overall suggests a quickened R&D process. Speed is the hallmark of commercial research firms allocating resources to maximize the period of monopoly revenues. They add researchers to speed research. Thus, patents with more co-patentees predict (a) fewer academics and (b) lack of an academic assignee. Furthermore, assignee and number of co-patentees add nuanced impacts to inventors. Obviously, institutions are active, decision-making characters in the innovative process. They participate in the inventive process by augmenting research via allocation of research resources, including people. Thus, how much they impact shows the nuance of the academic co-patentees innovative activities.

3.5 Statement of Hypothesis

Given the above-stated augmentations and novel attributes, the hypothesis of this dissertation answers the research question, "does co-patentee networks' composition indicate that Japan's academics' practice of transferring intellectual capital to drug commercializers was changed by Bayh-Dole?" The hypothesis is as follows:

Pharmaceutical industry commercialization data (from the United States Federal Drug Administration's Orange Book of Approved Drug Products with Therapeutic Equivalency Evaluations with augmentation from United States Patent and Trademark Office and academic and professional media) show network indicators (academics' participation among each patent's co-patentees and assignees in an environment of speedy innovation) of Japan's academics' (compared to America's academics) value-adding practices from their intellectual capital (when Japan's academics choose to divest their intellectual seed(s) and consultations founding a patent to a commercializing firm) demonstrate that introduction of Bayh-Dole-type (Japan's Industry Revitalization Law and America's Patent and Trademark Law Amendments Act) administration to Japan's national innovation system results in no detectible change in pattern of network dynamics that constitute a value-adding practice. This uses network indicators of drug innovations to answer if Japan's reforms' had any impact.

Thus, the hypothesis tests three inputs that show that Japan's Bayh-Dole policy results align with America's. In addition to academics' participation alone, two other components augment the test. One is whether inventors' work affiliations connect to their patents' affiliation to a like institution. Namely, are academics' patents assigned to universities or public research institutes? The other is whether the number of co-patentees relates to the co-patentee groups' affiliative composition. To the extent that commercial firms value speed, adding researchers to projects optimizes innovation, so number of co-patentees would increase. Put simply, do patents with co-patentee groups that are populated by smaller ratios of academic researchers tend to have only commercial assignees? Together, these three components test the distinctiveness and character of Japan's and America's academics' speed of divestment of their inventive seeds; thus, allowing conclusion on whether Japan is out-performing, under-performing, or converging with America's results.

3.6 Conclusion

Therefore, does co-patentee networks' composition indicate that Japan's academics' practice of transferring intellectual capital to drug commercializers converge with US results, which show no conclusive determination of any significant impact? Legacy literature and preliminary analysis show the question is answered with confidence, accepting:

- The source data provides confident international comparison, American and Japanese performance being normal to one another

- Proportion of public patentees and presence of academic assignees correlate as do commercial assignees with more co-patentees, so quickened patent production
- Earnings come from the actual market, but academia trades on potential earnings.

Accepting these, the question of Japan converges in its being unsuccessful. The common view is that Japan lags behind America. Another is that Japan fails, but so does the US, so their results effectively converge. Test results are expected to concur with the latter view, that neither country's Bayh-Dole type policies have resulted in academics adding value to the innovative process.

4 Methodology

4.1 Introduction

Selecting a test method demands fit between both the research question and the source data asked to answer it. Questioning academics' innovation process meant finding a data-source that could provide answers and finding the right method to bridge from that question to its answer.

This dissertation's began by questioning "how do rule changes make innovation practices evolve?" Asking this is unremarkable. It was addressed in prior academic research (Mowery *et al*, 2004)(Sampat, 2006)(Aldridge and Audretsch, 2010)(Hall, 2005)(Lach and Shankerman, 2003)(Azoulay, May 2005). What is remarkable is the source data found, but unused for research on the innovation process.

Herein, data from the United States Food and Drug Administration's Center for Drug Evaluation and Research's Orange Book of Approved Drug Products with Therapeutic Equivalence Evaluations and augmented by data found in patents and on patentees' and assignees' professional affiliations, allow micro-economic network analysis. That Orange Book's approval for public sale fits how the OECD defines innovation, which includes commercialization (OECD, 1997). USPTO patents name approved drugs' patentees and assignees locations while academic and professional media characterize each as academic or commercial. With the location and professional characteristics of each innovator person and institution entered, the data leads from the above general question to this dissertation's hypothesis: does co-patentee networks' composition indicate that Japan's academics' practice of transferring intellectual capital to drug commercializers was changed by Bayh-Dole?

In legacy network analysis, the accounts of patents, citations, geography and cash flows, and the questionnaires of managers and inventors offer partial, obscured or biased insights on innovation. By contrast, co-patentee and assignee data from US approved drugs offers a quantitative source with unmatched comprehensiveness, transparency and authenticity. Change in the proportion of academics within discrete inventive groups is not obscured (Is transparent) or biased (Is authentic). Further, though the data is large, sampling (versus comprehensive) is unnecessary, because the whole population of USFDA approved drugs' patents' patentees' and assignees' affiliations is openly available or readily discernible. Thus, with its authenticity, transparency and comprehensiveness,

this dissertation calculates inventor networks' professional composition so as to approximate the speed at which universities transfer ideas to commercial enterprises.

This section explains two methods. First is the method to compile the database's content. Second is how statistics on each tested characteristic are collated. Collation of compiled database content informs the analysis of this dissertation.

As noted in the Hypothesis section, test data is compiled successively from three different sources. One enters patent numbers, approval dates, and exclusivity terms defining drugs approved by the United States Food and Drug Administration's Center for Drug Evaluation and Research (CDER). Next, United States Patent and Trademark Office files date patents' grants and name and locate their inventors and assignees. Last, affiliations are fetched mainly in medical journals. The rationale for each step's components is explained along with its mechanics. Thus, dimensions of calendar time, group characteristics, and location are derived from three sources: the USFDA-CDER, the USPTO, and academic, professional, and popular searches to produce nine variables.

Collected data are collated for, first, descriptive statistics, then along two axes of analysis. Data is, first, tested overall for relationships among variables and for the data's attributes, such as number of observations, means, standard error, standard deviation, skewness and kurtosis, among others. Of the axes, one is for pre- and post-Bayh-Dole comparison of means, but within the national innovation system. The second axis is for Japan-versus-US comparison of means. Thus, by

understanding the peculiarities of source data's internal cohesion and the nature of the columnar relationships, such as time and policy changes on level of academicness among co-patentees, conclusions can be drawn on whether the time to transfer of inventive seeds to commercial enterprises has changed between before and after Bayh-Dole in Japan and the US and the level of trust in those conclusions can be derived.

How do rule changes make innovation practices evolve? Given reliance on pharmaceutical data, does co-patentee networks' composition indicate that Japan's academics' practice of transferring intellectual capital to drug commercializers is changing and is converging with US practices? These questions are answered by testing difference of means between Japan's and America's innovators plus factors that augment accuracy of the micro-economic network results. Presence of assignees that are academic institutions and the number of co-patentees are augmenters. Deviations in data plot norms are anticipated, but deemed parametric under conditions of the central limits theorem. Thus, the methodology utilized for testing has two facets, data-sources' integration, assumption of parametricity, and difference of means, which are each lend both sophistication and complications to the test regime.

4.2 USFDA-CDER

4.2.1 Introduction

As previously mentioned, this dissertation asks how Japan's academics' innovative capacity compares to America's. The USFDA's Orange Book of Approved Drug Products with Therapeutic Equivalence Evaluations fully lists all patents reported from all US-approved drugs. They were first reported in 1984. Given patents' 17-year span, 1984-patents draw may precede the 1980 Bayh-Dole Act by up to 14 years. The Orange Book is comprehensive, transparent, and authentic to (a) to US law, which demands actual inventors be named, (b) well over 60 percent of TTO revenues accruing from medicine (Cockburn, 2009), and (c) the US market attracting all of Japan's pharmaceutical inventions possible under US law and patent rules, just as are America's. It is the optimal source for "apples-to-apples" comparison of each of Japan's and America's academics' innovative capacity.

4.2.2 Compilation of Approval Data

To test the innovation system requires identifying documented, testable innovations. US approved drugs give this. Macro-economically, since America demands transparency for reasons of informed consent in its drugs and to enhance dissemination of novel capabilities for patentable products, innovations' documents are freely accessible from the USFDA. Such detail is more consistently available in pharmaceuticals than in other industries that lack the public welfare demands against

secrecy. Micro-economically, since (a) patents currency for disclosure is exclusivity, (b) diligent disclosure offers legal protection and (c) the US market generates huge revenues, US drug innovators benefit from disclosure to an extent that trade secrets cannot replace. Thus, sourcing innovation data from pharmaceutical sales in the United States provides unparalleled comprehensive content for the network analysis of academic intellectual capital retention, a practice that adds value. The United States Food and Drug Administration-Center for Drug Evaluation and Research's Orange Book of Approved Drug Products with Therapeutic Equivalence Evaluations provides details on approved drugs, but incompletely on their innovation process. The most informative ones are new drugs' patent numbers, by which patent contents' information is subsequently gathered. Other data are each drug's name, date of approval and date that exclusivity ends. Drugs' names help count distinct approvals and link all of each one's patents. Patents used in multiple drugs are still only invented once, so are catalogued only to the earliest drug, alphabetically. This stops double-counting. Both dates are legitimate alternatives for time-referencing, so the choice is discussed in the upcoming "Timing and Complexity" sub-section. Finally, from patent numbers, two more levels of data collection arise—data from the patents and then on the patentees' affiliations. Thus, four types of data from the USFDA-CDER Orange Book offer the base upon which each next tier of data collection on network characteristics builds.

Note that approval of drugs for sale constitutes innovation, as defined above. Approval stands as commercialization's full proxy, so innovation. Testing the innovation process, though, asks that its factors be documented and not derivative; testing counts academic inventors representation among co-patentees. That ratio indicates value-adding retention of ownership of inventive seeds. While, compiling ingredients is a prerequisite of creating deliverable drug therapies, its artistry is inconsistently published, not scalable, and derives from others' inventions and new molecular entities. "Development" is unquantifiable and derivative compared to "research." Counter-intuitively, though, counting innovations misrepresents the innovation process. Many drugs share patents, so otherwise comparable inputs get distorted by multiple counts. Thus, patents of innovations, not the innovations themselves, are the denominators of measurement. USFDA approval is fundamentally a vehicle for identifying innovations' founding inventions.

4.2.3 Conclusion

As the value-adding measurement is by network analysis, which is a non-financial metric, innovative capacity, not revenue, scores value to compare Japan's academics to America's. Network analysis data is derived by combining information from USFDA-CDER-approved drugs, their patents, and those patents' co-patentees including all from 1965 to 2012. Data present there is comprehensive, transparent, and authentic to actual inventors, academia's main industry for generating revenue, and full equitability in presence of Japan's and America's drugs. Methodologically, approved drugs add

identity drug innovations, their timing, and their patents.

4.3 USPTO

4.3.1 Introduction

Orange Book data alone is insufficient to derive academics' innovative capacity. Scholars, groups and timeframes need be identified to invest characteristics sufficient for network analysis (Powell, 2009). Two more steps add identification. First, the Orange Book's patent numbers are searched in the USPTO database. It shows each patent's patentees, assignees and granting date, which are catalogued with dates and assignees' and inventors' names and locations. Secondly, assignees' and inventors' academic or commercial affiliations are determined using search tools. Aggregating that data completes cataloguing co-patentees' professions.

4.3.2 Compilation of Patent Data

Patents offer a limited amount of information that aids assessment of innovative capacity via analysis of networking. Co-patentees, assignees, and citations are named and filings, grantings, and publications dated. However, citations and publication dates, which constitute artifices of the patenting process, not the innovative process, are irrelevant to this dissertation's analytical framework (Lanjouw, Pakes and Putnam, 1996), which is concerned with only inventors and innovators, including their locations and their time references. Consequently, only patentees' and assignees' names and locations and dates when patents were conferred are entered into the database

from patent source-data.

4.3.3 Conclusion

To create a new integrated database for testing the above-stated hypotheses using network analysis means identifying innovations' inventions. Gleaning all the USPTO patent numbers that were identified in every USFDA-CDER's Orange Book's patent and exclusivity addendum, from the first to the present, accounts for those innovations' inventions. This dissertation's database includes all patents from all drugs approved between 1984, which was the first year that the Orange Book included patent data, to 2012. The database for this dissertation's research begins with the so-derived comprehensive list of USFDA generated drug innovations' patents, using those numbers to source the specific identities and locations of their inventors and assignees from the United States Patent and Trademark Office's patent databases. With the inventors being named, timed, and located, the cross-referencing of those results with academic and professional publications is the next step, which is the identification of institutional affiliation. Generating affiliation data is accomplished after a detour to select among the four options that designate inventive and innovative timing.

4.4 Timing and Complexity

4.4.1 Introduction

From the United States Patent and Trademark Office, all of its granted patents are chronicled and freely availed to public scrutiny. Methodologically, pertinent details from patent documents are accessed using the USPTO's online search portal. Details garnered include the names and locations of both assignees and patentees, and patents' dates of issue.

In instances where more than one functional permutation of USFDA-CDER and USPTO data could inform any of the three axes, the choice deemed most accurate was selected. The designations of calendar time, identification of assignees, and characterization of inventor networks each have options. Each omission and extrapolation is disclosed and explained below. Thus, the precision of plotting value-adding practices over time on those three axes is maximized.

4.4.2 Timing

In simple terms, this testing compares pre- to post-Bayh-Dole academic innovation. To separate Bayh-Dole's effects from other temporal effects requires that a measure be established. Source data offers several options, one at the innovation level and three at the invention level of analysis. The Orange Book gives the date (a) when FDA-recognized exclusivities end. Patents have three dates: (b) application, (c) confirmation, and (d) expiration. Relevance to networking during the innovative process is essential for an acceptable measure; beyond that hurdle, maximum consistency

vets the optimal choice.

Among the four choices, two stipulate exclusivity's termination. First, the Orange Book's end-points mainly derive from their patents, but special FDA rules, as for children's medications, extend some. Second, mid-1995, USPTO law added a "whichever is longer" provision that defies consistency (a) either side of 1995 and (b) among those afterward. For relevance, duration of exclusivity affects business interest in, support for, and management of the innovation process, but not inventiveness. Thus, neither relevant nor consistent, exclusivity end-date options are rejected.

Of the remaining two choices, patent applications seem like untainted measures while the patent grant date appears exogenous. Applications are the only dates where the inventors' and/or assignees' chose timing, yet, since challenges from examiners and alterations from inventors initiate revisions, they act inconsistently among patents after application. Once a patent is issued, however, its contents are fixed. Its inventive process has truly ended. Any further modifications accrue in separate patents. Prior to a patent being granted, additions, omissions, and modifications effectively negotiate a date in anticipation of which the inventors, assignees, and examiners all agree to end innovation. Legally, each character has some power over this process. Thus, the date on which patents are issued is both relevant and consistent as a measure and among all patents.

Patents' application, confirmation, and expiration dates and end of FDA exclusivity were each considered for consistency and relevance during innovation. The date on which the USPTO

confirms issue of patent rights achieves both relevance and the highest degree of consistency among the four options available from the USFDA's Orange Book and the USPTO's patents. As a result, the patent issuance date is the measure selected for this research's database.

4.4.3 Complexities

Some patents' assignment shows deficiency and complexity. While most patents name both inventors and assignees, some lack explicit assignees. This indicates that the inventors retained assignee rights (Fleming, Mingo, and Chen, 2007), so this research adds them. In cases where assignees are plural, diversity among inventor-assignees' nationalities and affiliations complicates identification. With multiple institutional assignees and the above-mentioned inventor-assignees, any assignee diversity is addressed in the same way.

4.4.4 Conclusion

Among rival data choices, this section showed the most useful time-measure and assignee cataloging. In each case, accuracy determined selection. Patent grant date is used for all time-reference coding, because they are consistent and describe the legal end of the inventive process. Oddities without named assignees are transcribed as patentee-assignee.

Once each patentee's and assignee's affiliation is ascertained and grouped with fellow patentees, groups' academic-affiliated proportion is calculated. Academic character of the co-patentee nodes are the micro-foundations that, aggregated, generate macro-economic results of academic

inventiveness within a national innovation system. That plot shows Japan's and America's realized innovative capacity trends by descriptive statistics that consider group size and composition over time as shown in approved drug data.

4.5 Inventor Networks

4.5.1 Introduction

The above data is not new. However, legacy literature either defined sampled patents as innovations or tracked few verifiable innovations' patents in case studies (Lanjouw and Lerner, 1997). The former misidentifies patents as innovation. The later applies numbers of innovations, patents, and inventors that are too low for statistical significance. They are case studies, not econometric analyses. This dissertation circumvents those flaws by sourcing innovations data from a mass source, the USFDA-CDER Orange Book of approved drugs.

Orange Book data solves many of these problems and provides a means to circumvent the remaining flaws. As a data-source, using USFDA approvals appears novel for non-medical applications, but this dissertation also able to add the tracking of academics' innovative process through the links to those drugs' USPTO patents and those patents' stated assignees' and inventors' location and affiliation. As such, the shared character of individual co-patentees is expressed as a nuanced network that indicates the way that the inventive portion of the innovation process unfolded.

Network characteristics show how innovation occurs. In the inventive portion of drugs' innovation

process, academic researchers may initiate inventive seeds or contribute such novelty as completes an invention's utility. Said contribution may be as scholarly colleagues or as external consultants to commercial or outside academics' research. Inventors are identified in each patent's co-patentee group and that co-patentee group constitutes an inventive network. Since, as shown above, academic researchers displace commercial researchers, so the more academia in co-patentee groups, the more complete is their research work's dominion over available innovative capacity. Patent law designates the seed-to-patent process as zero-sum; all inventors, or their assignee designates, have fully independent rights to the intellectual property for purposes of commercialization. Thus, determining academic versus commercial affiliation becomes a central variable. As such, after garnering approved medical therapies' patents from the Orange Book and their dates, assignees and inventors from the USPTO, whether those institutions and people are academic needs be determined. Adding the dimension of their affiliation—academic or not—adds data for an abundantly novel analytical framework.

4.5.2 Assignee Affiliation

Assignees' affiliations are easily found. They self-identify affiliation for legal and market reasons: corporations adding "incorporated (Inc)", "limited (Ltd)" or "limited liability company (LLC)", schools, "university" or "institute of technology". Where names are indistinct, verifying information from their "About Us" web-pages and external news reports is used. Firms profit

motive bridges capital investments to sales of disposables with research that translates those investments into marketable products. Meanwhile, academic institutions derive value from scholarly integrity attracting students, vanguard research helping attract them. Education anchors academics' integrity outside commerce. Therefore, by name or "About Us", whether an assignee is an academic or not is ascertained.

Three complexities are present among assignees: no, multiple, and intermediary entries. Where no assignees are named in USPTO documents, assigneeship is retained by the inventors (Fleming, Mingo, and Chen, 2007). For this dissertation, each inventor-assignee is treated as a partner-assignee, no different than a firm, because USPTO representation makes no distinction and their function is legally identical. Likewise, multiple firms are treated as partner-assignees. Any one partner-assignee being both academic and from Japan or America gets deemed academic. Intermediary institutions, such as non-profit or government-sponsored research institutes or as private hospitals, which, like private universities, are for-profit, also earn integrity by vesting in patients, not pharmaceuticals distribution and retail. These intermediary institutions are reported as academic.

4.5.3 Patentee Affiliation

Lacking helpful titles or "About Us" identifiers, inventors require more options, care, and flexibility in determining affiliation. Two types of source and, thirdly, a method distinguish academics from

others. For compiling this dissertation's data, the most trustworthy, precise and redundant verification for each named inventor is utilized, so, where names affix affiliations, the pairing with most qualified and numerous identifiers is accepted. The top source is academic and professional journal articles. The second is unofficial representations, such as professional networking systems and news reports. Finally, where a name lacks any matching academic or professional authorship and non-journal sources either provide no match or no definitive match (as with too many overlapping names, none of which appear to match the stated character of the inventor) outside patents, that inventor is ascribed a "patents only" designation. As a result, each inventor's name's most informed identifier is used to set him or her as an academic or not.

Nonetheless, several types one and two errors threaten. Identifying the potential threats and addressing their mitigation, reduction, or elimination benefits the reader's understanding of the limits of methodology that relies on the gathered data. Specifically, variation of names, academic and professional publications, networking and news reports, and "patents only" designation are explained.

Variation of Names: For various reasons, names may be written differently in different sources, a confusion that could lead to incorrect assignment of academic status. Portions of names, such as middle names or initials, are applied to authorship somewhat unpredictably. Some people use their middle name and ignore or reduce to an initial their first. Also, full names are reduced to initials in

some journals. Addition of "Jr." or "III" occurs occasionally, but may be applied inconsistently between sources. Similarly, some nicknames or shortened versions of names are present. People of certain ethnicities, such as Chinese, may adopt and use a Western-style or Western-derived name in addition to their true name or, as with Indians, shorten their actual name to a nickname accessible to native English speakers. During the process of searching for matches, these derivations are taken into account by progressively testing alternative names when the one provided by the USPTO proves unavailable or indeterminate.

Academic and Professional Publications: Journals are professions' most trustworthy sources. With (a) publish date, (b) author names and affiliations, and (c) topic and its category, and high trust, journal articles are affiliation's preferred corroborator. Using specialized search engines Google Scholar Advanced™ and Microsoft Academic Search™, each patentee's name is diligently checked. However, common names increase the likelihood of overlap, so causing false positives from misidentification. Diligence countering these miscues is achieved by narrowing search parameters. First, only three types of content are searched: medical, chemical, and biological. Second, matching characteristics in USPTO data are best when matching in three areas: date, location, and assignee. Closer matches earning priority. The inventor or co-inventor may be the assignee's employee. Thus, maximal number and proximity of references shared by both USPTO data and that found in articles sets the priority for identification of the actual inventor among would-be

journal article authors.

Networking and News Reports: A second two sources confirm affiliation come from outside research documentation. One is news reports, which have lower verification standards than do journal articles. These include magazines and newspapers, releases and disclosures from governments or firms, and even obituaries. Self-reporting is second, namely from professional networking sites and resumes or curricula vitae. Top among networks is Linked-In™, which provides a level of professional detail and history absent in general social networking sites or topical sites with a focus other than profession. Defining affiliation from these sources increases the possibility of false-positives like misrecognition of people with similar names, so secondary qualifiers, such as date, location, and overlap with the assignee, add corroboration. When the previous two types of source are unavailable, then this research turns to networking and news report data.

Patents Only: As said above, this research measures academics. The currency of academia is amount and quality of research as recognized in publishing. Thus, lack of publications indicates that an inventor is likely not an academic, which this research method identifies as "patents only" for affiliation. However, false positive scenarios of (a) age, (b) newness, and (c) Japanese deserve note.

- **Age:** Inventors who only patented in the distant past, long before the rise of the internet, may lack digitized publications. Search engines rely on digitalization, which started from the then-present and backtracked into legacy material. However, the transfer of legacy journal articles is very advanced in medicine and pharmacology, so a relatively minor limitation.
- **Newness:** New academics' may yet be unpublished. Since few graduate theses are widely published, those academics may appear absent. As this is a real problem, not one sourced from awaiting digitization, it can only be overcome by time until would-be academics publish a body of research. Nevertheless, their number appears so few that it is unlikely to impact results significantly and can, to some extent, be reduced by checking non-journal sources, like news or professional networks. Additionally, publication precedes patenting, because the process is shorter.
- **Japanese:** Language and culture barriers may hurt Japanese academics representation. This problem, too, is real. Its deficiency is partly reduced now that researchers gain more professional recognition in Japan from their overseas publications. Those from before Japan came to appreciate it and from new researchers writing in Japanese first are likely under-represented. However, because untranslated texts are present from search engines, particularly in citations entered in newer articles and as recent publications often include an English-language abstract, Japanese-language false negatives appear insignificant.

Thus, while recognizing the structural limitations mentioned above, for academics for which no definitive affiliation can be found, a non-academic "patents only" affiliation is entered into this research. This is because having only patents suggests that the inventor worked for a firm, but never published while doing so.

An additional note on the content of the database is important. While analysis remains on participants of Japan's and America's innovation systems, as defined by their location in either Japan or the United States, foreigner co-inventors are also included in the measures. Where a patent's inventors include a Japan- or US-based inventor, all of the others are also counted and their affiliation provided. Their affiliation adds to the proportion defined for the whole team of inventors, so affecting the group's proportion that is, then attributed to its individuals. Nevertheless, only the Japan- or US-based academics themselves are counted for analysis of their national innovation systems. Considering their affiliations, but not their persons, reflects the richly international flavor of both academic and commercial research in the pharmaceutical industry and the innovative capacity that is present, but unrealized for academics within the national innovation system.

4.5.4 Conclusion

Thus, through sequential stages, errors are minimized. False negatives are avoided for all but the newest, oldest, and near absolutely nationally insular of academics. False positives are minimized to errors in USPTO records of inventors' names, a failure that is outside the scope of this dissertation,

and where academics with the same name and corroborating location and assignee are in greater synch with USPTO records than correct non-academics. All such false positives are radically reduced to insignificance by redundancies in the checking method.

4.6 Plotting and Testing

4.6.1 Introduction

Once built, descriptive statistics identify database content. This is divided into three levels: (a) innovations, (b) patents, and (c) patentees. Content that combines variables' data occurs at the level appropriate to its logic and then those plots are compared between Japan and America. Combined variables' data generates preliminary comparisons that are useful stand-alone content, but also includes exogenous effects that muddy understanding of co-patenting behavior. The result, however, limits its hypothesis testing to co-patentee affiliation plots assessed through differences of means analysis before and after each country's Bayh-Dole. Afterward, discussion turns to evaluation of the various plots.

4.6.2 National Innovation System Effects

National innovation systems operate under the terms and conditions present within that legally defined economy. In the case of this analysis, it is the national innovation system of Japan that is the object as it would re-order itself under the influence of its Bayh-Dole type law—the Industrial Revitalization Special Law. For purposes of contrast to a comparable economy with maximally longitudinal and full data available, the national innovation system of the US is used. Each

country's Bayh-Dole type legislation was intended to modify the legal structures underpinning market mechanisms within its national innovation system.

Inventors' stated location as represented in USPTO patent data is used to identify each individual inventor's national innovation system. Both approved drugs and patents may include patentees from outside Japan or the United States, while others have both Japan-based and US-based co-patentees. The network indicator function must include all members of the team, but rendering analysis down to national innovation systems must reduce expression of the network indicator function to only those patentees within a given national innovation system, like Japan or the United States. Surely, in the case of patents, co-patentees are part of a single network bounded by inventors named on the patents, so are included in approved drug and patent levels of analysis. However, when specifying the nature of individual patentees' behavior, those outside the national innovation system do not belong and are discarded. As such, by counting only patentees who locate themselves within the national innovation system, the effects within that system are inherently weighted to participants, even as they account for participants from without.

The actual process of plotting co-patentee data for each national innovation system's participant is straightforward. Each Japan-based and each US-based patentee counted as a member of his or her patent—a co-patentee of the given patent. Further, each said co-patentee's affiliation is counted. Affiliation is critical here, since it is they who are affected by the legal changes that arise from the

new policy. The ratio of academic researcher co-patentees to the total number of co-patentees is rendered for each patent. All patents that include at least one patentee from the object country are then plotted, first, between each national innovation system before and, separately, after the country's Bayh-Dole law came into effect. It is noteworthy at this point to acknowledge that Japan's law came into effect staggered over five years. It was first applied to non-National universities, then to National universities when their legal status was changed to make them independent commercial enterprises (that happen to retain the national government as their overwhelmingly chief shareholder). To compare those national innovation systems cross-sectionally, Japan-based and US-based patentees from before are compared using difference of means. The same cross-sectional test is applied to post-Bayh-Dole data. The second order of analysis is outlined below under "Bayh-Dole Effect". The resulting plots allow accurately nuanced measure of non-resident inventors on residents for difference of means comparison between co-patentees within the national innovation systems of Japan and the US.

4.6.3 Bayh-Dole Effect

The final step answers this dissertation's hypothesis that Japan- and US-based academics' intellectual capital practices across the Bayh-Dole horizon. It separates the descriptive data into that before and that after the law came into effect. All the previously mentioned derivations of input data are rendered within the patent-level analysis and aggregated for what can be termed

cross-sectional analysis. It is cross-sectional owing to its uniformly pre-Bayh-Dole or post-Bayh-Dole rank and disregards interfering temporal effects. This pre- versus post-Bayh-Dole data informs conclusions on Bayh-Dole effects within each of Japan's and America's national innovation systems. Thus, the Bayh-Dole effect is capable of being confirmed by comparing the pre-Bayh-Dole with those after it. Cross-sectionally, Japan and US plots show similarities and differences between how each country's national innovation system independently impacts on its inventors.

4.6.4 Conclusion

Thus, as the Literature Review explained, in order to compare the outcomes of the processes by which Japan's and America's university inventors commercialize their intellectual capital, this dissertation sources data overlooked in prior literature: the USFDA Orange Book, which is both germane to the majority of universities' intellectual property revenues and transparent and exhaustive within the field of approved pharmaceuticals and their inventors and employers. Analyses accrue from two steps. First, the resulting data that encapsulates patent-level analysis by co-patentees number, affiliation, and self-defined national innovation system is rendered to a difference of means test comparing Japan's innovated patents' against America's. Second, within Japan and the United States, completely ignoring the other, the data are tested for effects within Japan before and after Bayh-Dole legislation came into effect to confidently determine the difference

of means. Likewise, the same difference of means between America's pre- and post-Bayh-Dole characteristics are figured.

4.7 Conclusion

This research follows a path not found in legacy scholarship. Within the confines of pharmaceuticals, drug approvals near perfectly approximate the industry's commercial boundaries, whether on or off prescription. Their patents are a subset of all patents in their actually being applied to innovations, so have traction in the marketplace. Those patents' characteristics are, if their selection into innovations is random, at least a normal sample of all potential patents, but, to the extent that they aided innovation, in contrast to failed innovations, they offer insight into success inducing behavior. The behavior examined here regards the scale of intellectual capital, which is counted by how academic are innovations' patents' co-patentee nodes, as a proxy for the speed at which universities transfer ideas to firms that complete the research and development and then sell products based on them.

This Methodology section detailed two tasks. First was how the database's content was compiled. Second is how descriptive statistics on each tested characteristic is collated. Collation of compiled database content informs the analysis of this dissertation.

As noted, the database is compiled successively from three separate sources. One enters patent numbers, approval dates, and exclusivity terms defining drugs approved by the United States Food

and Drug Administration's Center for Drug Evaluation and Research (CDER). Two, United States Patent and Trademark Office files date patents' grants and name and locate their inventors and assignees. Three, affiliations are named mainly in medical journals. The rationale for each step's components is explained along with its mechanics. Thus, dimensions of calendar time, group characteristics, and location are derived from three sources: the USFDA-CDER, the USPTO, and academic, professional, and popular searches.

Descriptive statistics are collated in two ways. First, database content is tested overall for correlations among categories and for attributes, such as means and standard deviation. Second, difference of means analyses are developed into a four quadrant representation. One axis . Thus, by understanding the peculiarities of source data's internal cohesion and the nature of the columnar relationships, such as time and policy changes on level of academicness among co-patentees, conclusions can be drawn and levels of trust derived.

5 Analysis

5.1 Introduction

Analysis progresses, first, through statistics that describe the database's contents, then, in turn, the two steps mentioned previously: national innovation system effects and the Bayh-Dole effect. Preliminary descriptives show the number of patents, assignees, and patentees in Japan and the United States of America by year and aggregately, and give the numbers and proportion of

academics among co-patentees. More sophisticated descriptive statistics are presented graphically. Those descriptives offer insight into the constitution of the variables that underlie this dissertation's analysis. Difference of means comparisons for Japan and US patent-level data. This is done on two axes, one that of the national innovation systems and the other checking the impact of Bayh-Dole type policy change. One is within-country contrast of the before- and the after-Bayh-Dole means denotes whether internal change occurred in each of Japan and the US. The other is between Japan before its Industrial Revitalization Law and the US before Bayh-Dole, and then the same between-countries contrast is assessed for after those respective legal changes. Thus, the above-stated range of descriptive and analytical statistics is presented below.

5.2 Descriptives

5.2.1 Introduction

Descriptive statistics show the characteristics of the data upon which subsequent descriptive statistical analysis is based. The sources for the data contained in this dissertation's answering of the hypothesis are included as basic content. Most significantly, that root data shows how Japan data has a much less numerous scale than the US data, despite equanimity of temporal and multivariate data scope. Next, a mix of sometimes sophisticated descriptions are presented, including mean and standard deviation. Those measures are presented in tabular form. Thus, the statistical weaknesses inherent in the data collected, notwithstanding that it is a population, not a

sample, are illuminated prior to engaging in their analysis by inferential statistical methods, which follows this section on descriptive statistics.

5.2.2 Content

The data that this dissertation utilizes is described below. Its descriptive statistics track the scope of each numerically and, where helpful, graphically. Foremost, this description demonstrates the depth of this dissertation's foundations in quantitative data. The following, then, summarizes and assesses data provided by the new, large scale and three-source scope database used in this dissertation. Descriptive statistics calculations come from data exemplified in Appendix 1. The following lists of figures are provided for consideration and comparison.

- Total Number of Innovation Entries: Japan-92, US-888, Jp&USTotal-980 (7 include Jp&US co-patenteeships, so have been double-counted)
- Total Number of Patent Entries (Japan and US): Japan-218, US-2285, Total-2503 (37 include Jp&US co-patents)
- Proportion of University-assigned Patent Entries (Japan and US): 156/2503 = 6.233%
- Total Number of Inventor-Patentee Entries (all countries): 11,379
- Total Number of Inventor-Patentee Entries (Japan & US): 7318
- Total Number of Inventor-Patentee Entries by Nation: Japan-784, US-6534, others-4061 Germany(incl.FDR&DDR), France, UK, Netherlands, Belgium, Canada, Australia, Sweden,

Norway, Finland, Ireland, Bermuda, Poland, Switzerland, Spain, People's Republic of China, Republic of Korea, Italy, Denmark, Austria, Puerto Rico, Israel, India, Chile, Panama, New Zealand, Czechoslovakia/Czech Republic, Argentina, Soviet Union/Russia, Mexico, Egypt-4061

Figure 1a: Pharmaceutical Industry Innovations' Patentees

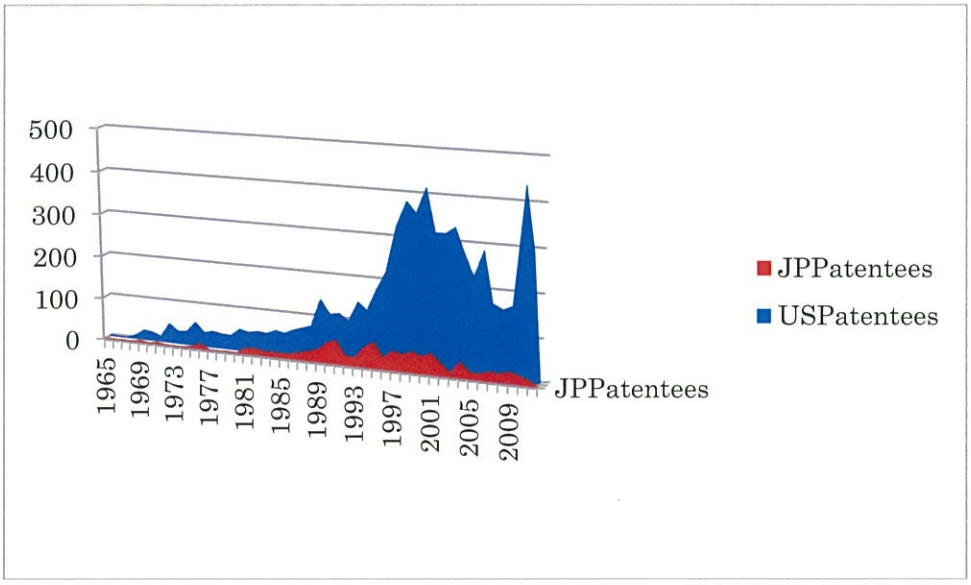


Figure 1b: Pharmaceutical Industry Innovation's Patents

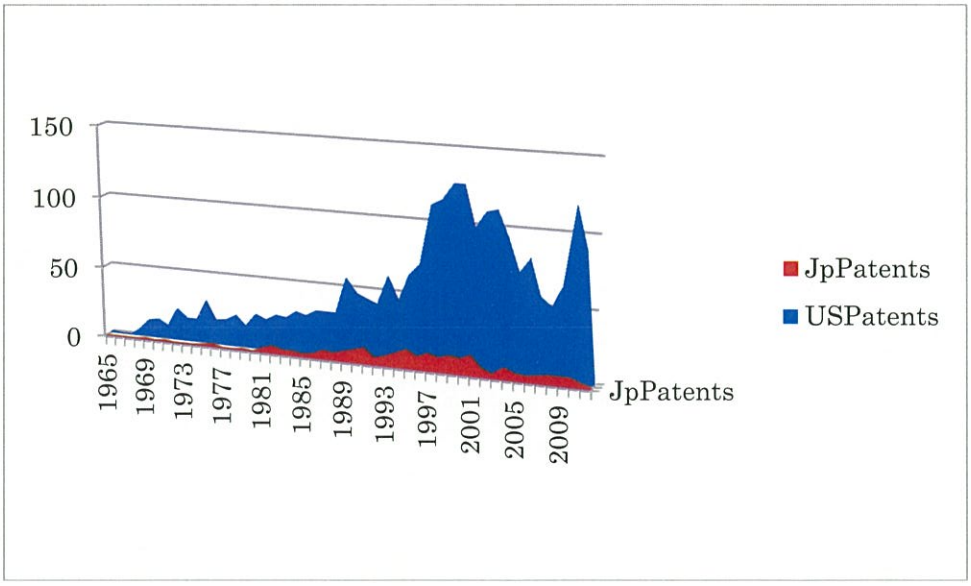
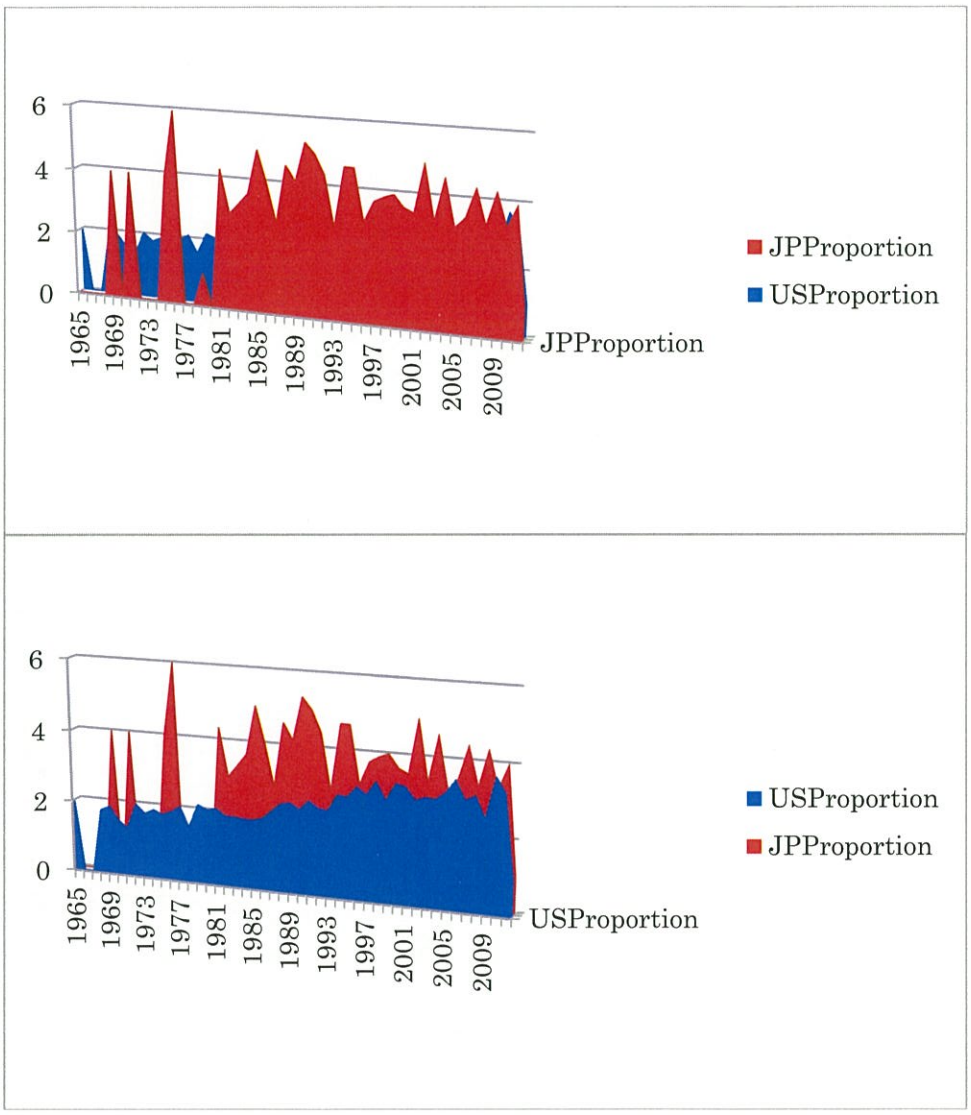


Figure 1c/1d: Pharmaceutical Industry Innovations' Proportion of Patentees to Patents



Total Number of Japan Patentee Entries: 734

Number of Japan's Discarded Non-Japan Co-patentees: 97

Proportion of Japan Patentees with Academic Assignee: 0.136%: 1/734 (Jp University) + 0.545%: 4/734 (Japanese Hospital) + 0.272%: 2/734 (US Research Institute) + 0.954%: 7/734 (total)

Proportion of Japan Patents with Academic Assignee: 0.459%:1/218 (Jp University) + 0.459%:1/218 (Jp Hospital) + 0.917%: 2/218 (US Research Institute) = 1.835%: 4/218 (total)

Number of Japan Patentees when Commercial Assignee: 727

Total Number of US Patentee Entries: 6534

Number of US's Discarded Non-US Co-patentees: 283

Proportion of US Patentees with Academic Assignee: 2.556%:167/6534 (US University) + 0.230%:15/6534 (US Hospital) + 1.255%: 82/6534 (US Research Institute) + 0.673%: 44/6534 (privately held) = 4.714%: 308/6534 (total)

Proportion of US Patents with Academic Assignee: 4.026%:92/2285 (US University) + 0.394%:9/2285 (US Hospital) + 1.444%:33/2285 (US Research Institute) + 0.700%:16/2285 (privately held) = 6.565%:150/2285 (total)

Number of US Patentees with Commercial Assignee: 6226

Total # of Japan Patent Entries: 193 (Japan Assignees), 26 (Non-Japanese Assignees) = 218

Total # of Japan Patent Entries with Japan Academic Assignee(s): 4/218

Figure 1e: Total Number of Japan Patent Entries, with Japan Academic Assignee(s), by Year: 1:1981, 1:1987, 1:1993, 1:1994

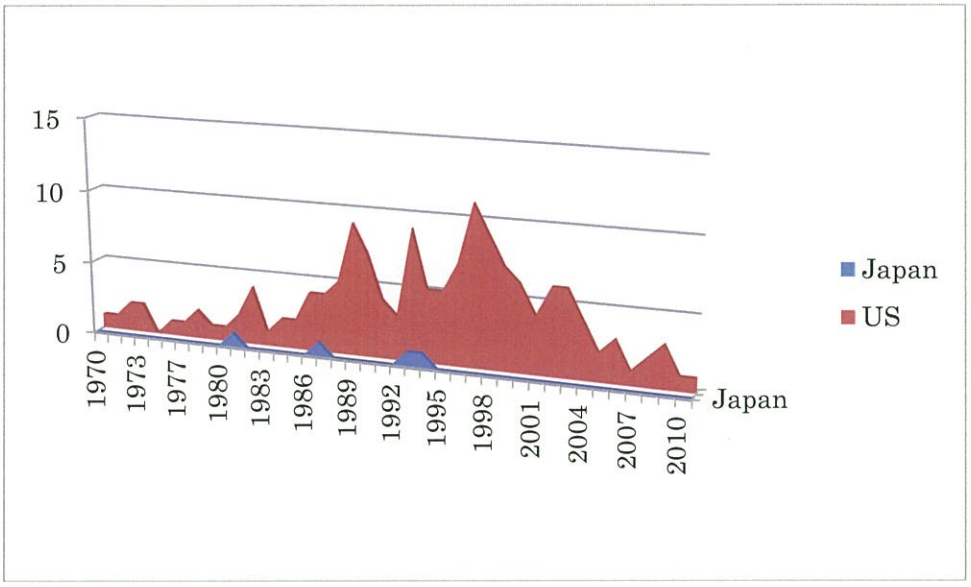


Figure 1e graphically shows the difference in number of academic institutions in Japan that act as assignees compared with the number in the US. Given that the US produced 10 times more patents from which to source information on assignees, the numbers are easy to misinterpret as Japan producing few assignees. However, given the 10:1 ratio, the conclusion should be that Japan produces significantly fewer (less than half) that of the US numbers.

Total # of US Patent Entries: 2285

Total # of US Patent Entries with US Academic Assignee(s): 153/308

Total # of US Patent Entries, with US Academic Assignee(s), by Year: 1:1970, 1:1971, 2:1972, 2:1973, 1:1975, 1:1977, 2:1978, 1:1979, 1:1980, 2:1981, 4:1982, 1:1983, 2:1984, 2:1985, 4:1986, 4: 1987, 5:1988, 9:1989, 7:1990, 4:1991, 3:1992, 9:1993, 5:1994, 5:1995, 7:1996, 11:1997, 9:1998, 7:1999, 6:2000, 4:2001, 6:2002, 6:2003, 4:2004, 2:2005, 3:2006, 1:2007, 2:2008, 3:2009, 1:2010, 3:2011

Descriptive Statistics' Checks of Viability of Data include: mean and standard deviation.

Table 1a: Source Data Described: Combined Japan and US Data

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Proportion of public patentees among all patentees in a given patent (PubPateeYN/No.ofCopatees)	892	.080	1.000	.49605	.311208
Number of co-patentees (total number of patentees named)	892	1	22	3.83	2.418
Duration between PTO grant & FDA approval	892	651.00	11053.00	5718.9809	1133.43610
Valid N (listwise)	892				

Table 1b: Source Data Described: Combined Japan and US Data

Descriptives

		Statistic	Std. Error
Proportion of public patentees among all patentees in a given patent (PubPateeYN/No.ofCopatees)	Mean	.49605	.010420
	Std. Deviation	.311208	
Number of co-patentees (total number of patentees named)	Mean	3.83	.081
	Std. Deviation	2.418	
Duration between PTO grant & FDA approval	Mean	5718.9809	37.95025
	Std. Deviation	1133.43610	

Figure 2a: Source Data Described: Combined Japan and US Data

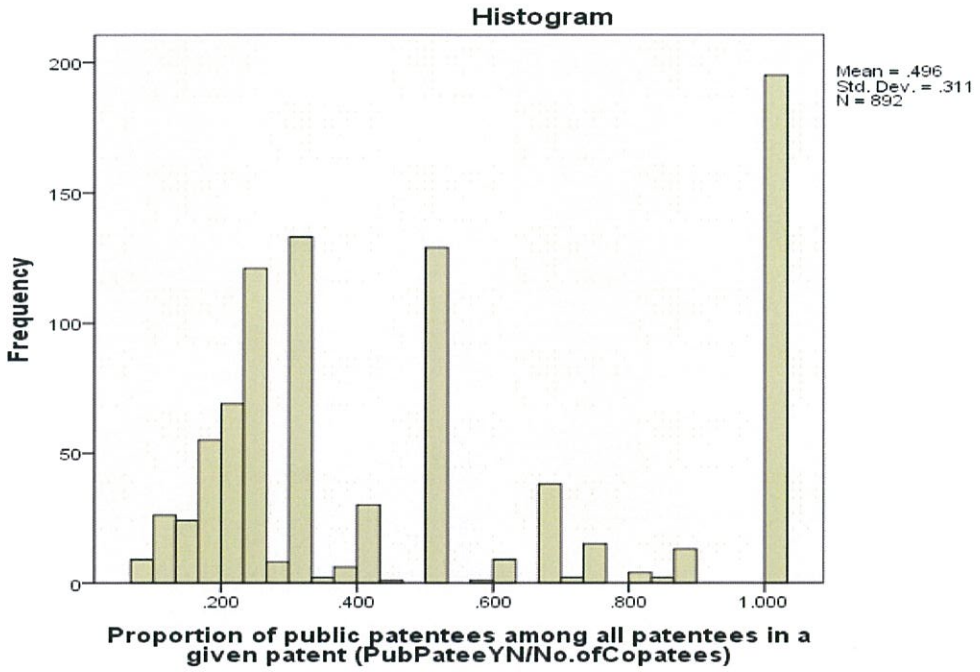


Figure 2b: Source Data Described: Combined Japan and US Data

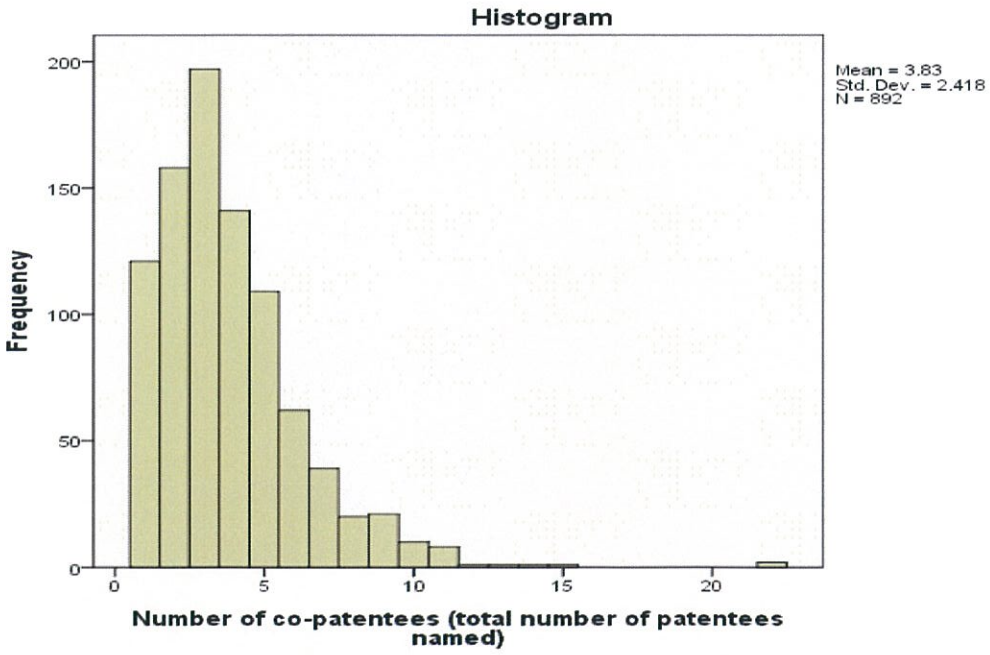


Figure 2c: Source Data Described: Combined Japan and US Data

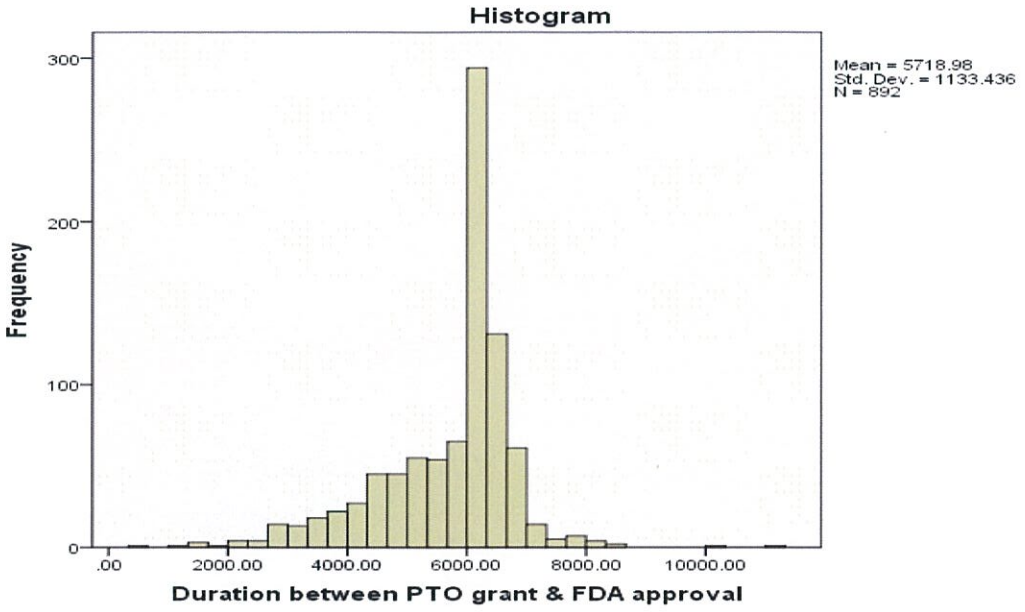


Table 2a: Source Data Described: Japan Data

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Proportion of public patentees among all patentees in a given patent (PubPateeYN/No.ofCopatees)	112	.080	1.000	.42786	.263625
Number of co-patentees (total number of patentees named)	112	1	14	4.79	2.341
Duration between PTO grant & FDA approval	112	2581.00	8458.00	6012.9375	1083.42597
Valid N (listwise)	112				

Table 2b: Source Data Described: Japan Data

Descriptives

		Statistic	Std. Error
Proportion of public patentees among all patentees in a given patent (PubPateeYN/No.ofCopatees)	Mean	.42786	.024910
	Std. Deviation	.263625	
Number of co-patentees (total number of patentees named)	Mean	4.79	.221
	Std. Deviation	2.341	
Duration between PTO grant & FDA approval	Mean	6012.9375	102.37413
	Std. Deviation	1083.42597	

Figure 3a: Source Data Described: Japan Data

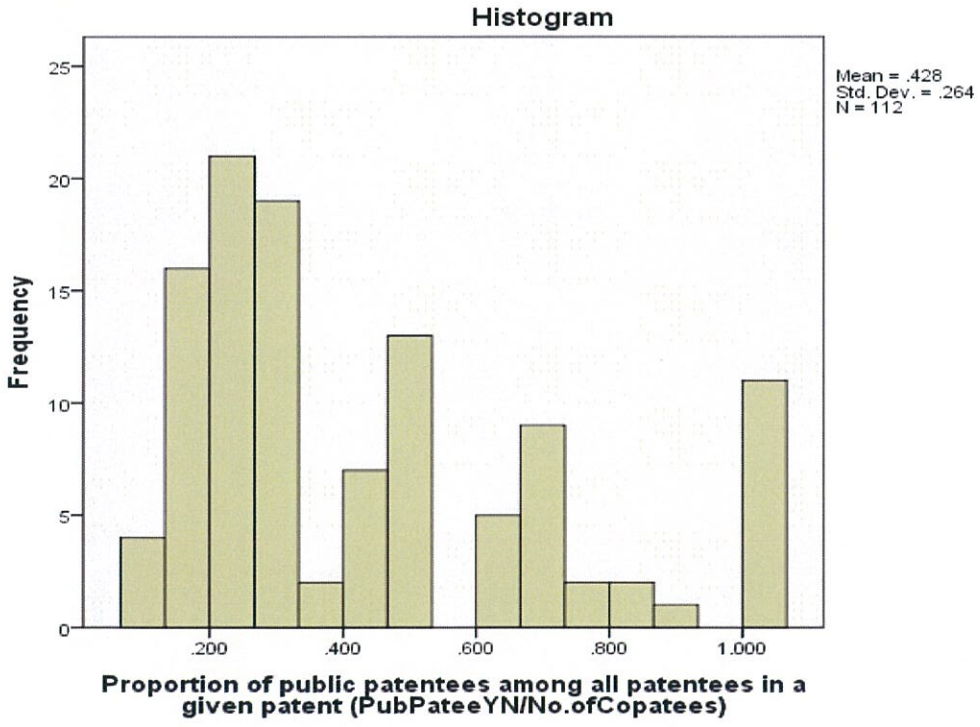


Figure 3b: Source Data Described: Japan Data

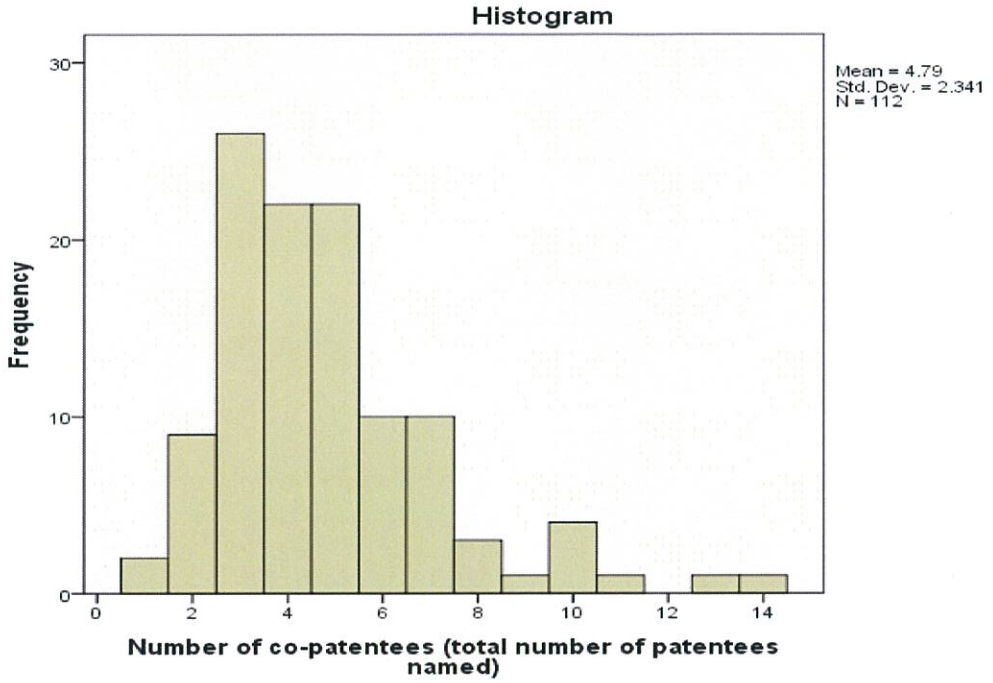


Figure 3c: Source Data Described: Japan Data

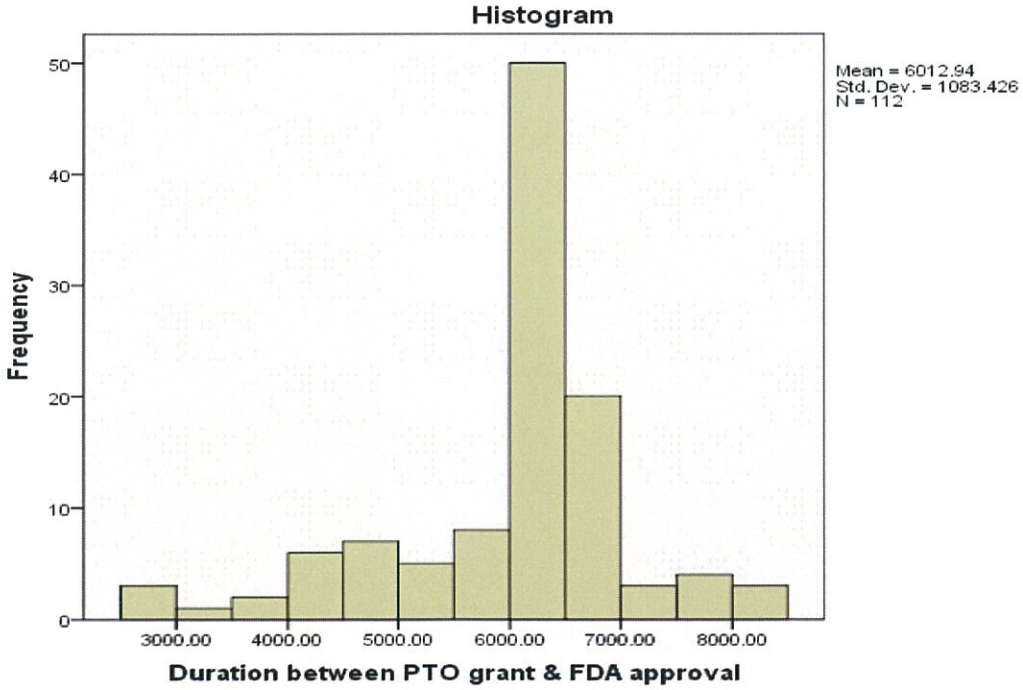


Table 3a: Source Data Described: US Data

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Proportion of public patentees among all patentees in a given patent (PubPateeYN/No.ofCopatees)	780	.080	1.000	.50585	.316398
Number of co-patentees (total number of patentees named)	780	1	22	3.69	2.399
Duration between PTO grant & FDA approval	780	651.00	11053.00	5676.7718	1134.86401
Valid N (listwise)	780				

Table 3b: Source Data Described: US Data

Descriptives

		Statistic	Std. Error
Proportion of public patentees among all patentees in a given patent (PubPateeYN/No.ofCopatees)	Mean	.50585	.011329
	Std. Deviation	.316398	
Number of co-patentees (total number of patentees named)	Mean	3.69	.086
	Std. Deviation	2.399	
Duration between PTO grant & FDA approval	Mean	5676.7718	40.63465
	Std. Deviation	1134.86401	

Figure 4a: Source Data Described: US Data

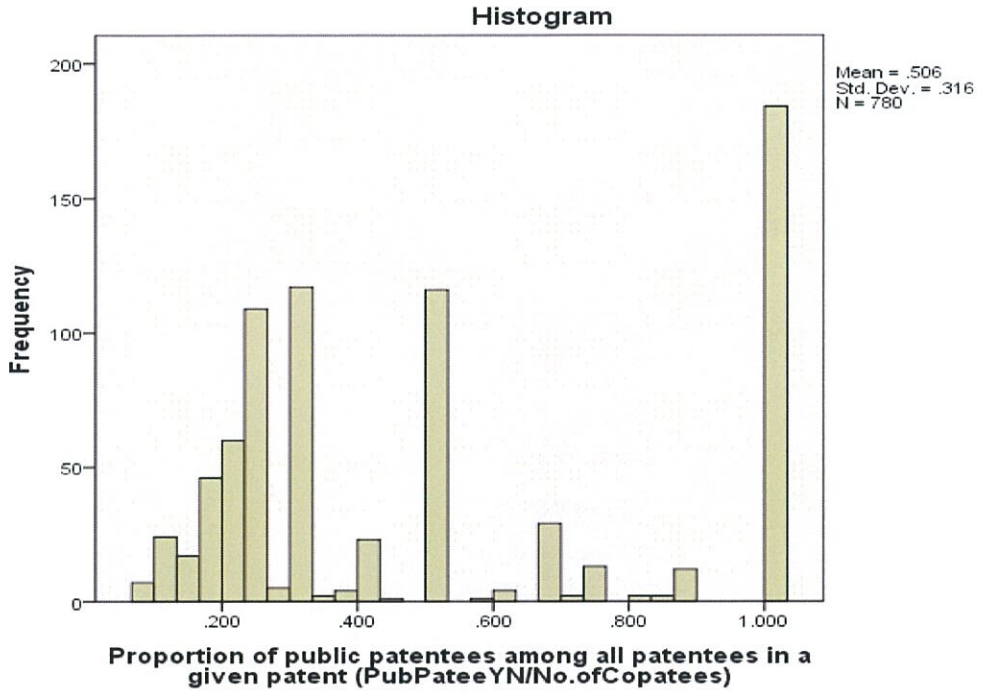


Figure 4b: Source Data Described: US Data

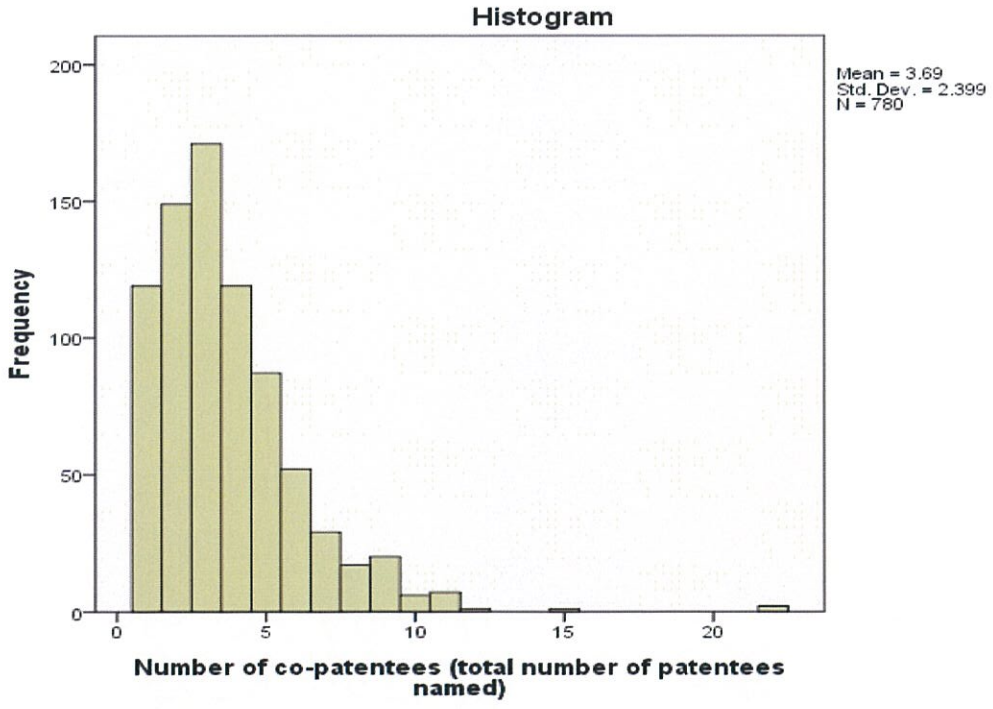
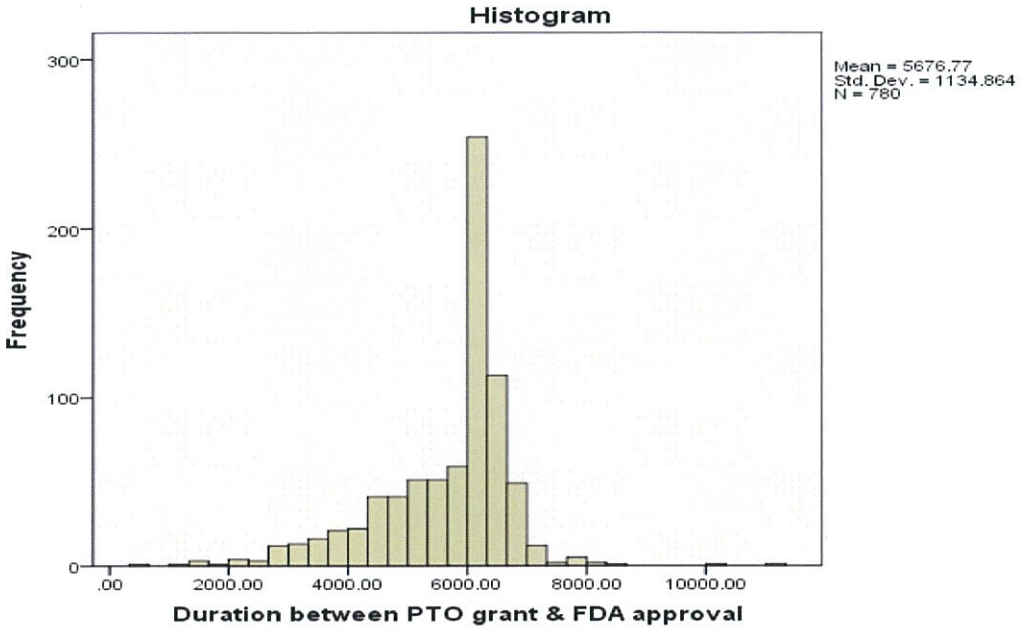


Figure 4c: Source Data Described: US Data



5.2.3 Conclusion

Data above describes the scope of the source data used in this dissertation. Where clarity would be enhanced, numerical representations have been augmented with the addition of graphs. Major findings show the difficulties of comparison and some of the warps within these populations. Notably, the number of Japan's entries is significantly fewer than America's and the number of US cases prior to Bayh-Dole is dwarfed by those after. Skew and kurtosis are noteworthy. Over time, the number of patents posted per timeframe trends larger in both countries. Japan's inventors tend to inhabit groups of between 3 and 7 people, while size of US teams shows no obvious size-preference (see Figures 1c and 1d). These characteristics add definition to analyses of the hypothesis.

5.3 Descriptive Statistics

Descriptives offer meager appraisal, which was mentioned previously. Its main purpose is to qualify the source data as sufficiently substantive as to legitimate further analysis. With a statistically significant number of cases for both Japan and the United States, it shows the data's fairness. Further, as the data is not a sample but a population, no sampling error is possible. Noteworthy is that it is time series data, not cross-sectional, with the incumbent statistical effects of time-series. These descriptives are the content-foundations upon which this dissertation's descriptive statistics build assessment in this section.

Such contents are divided into three levels of analysis, (a) innovations, (b) patents, and (c) patentees and assessed over two aggregative steps, assessment of (a) national innovation system effects and (b) Bayh-Dole effects. Once refined, this dissertation's hypothesis is tested through co-patentee affiliation plots for differences of means before and after each country's Bayh-Dole.

5.4 National Innovation System Effects

Individual patentees are the ultimate level of analysis, because they are the human creators of innovations' inventions and they personally reside in the tested national innovation system. They are innovations' undeniable source and this dissertation assesses and analyzes the academics among other co-patentees to explain the academics' relative ownership of the inventive process. Mating individual patentees within their co-patentee groupings demands that testing occur at the group level,

which, in this case, means at the patent level of analysis wherein inventor-level data is congregated. This analysis based on precursors to actual innovations is where this dissertation's research begins to diverge from Nooteboom's model and, in so doing, examines the innovation process more intimately. Part of that intimacy is that this dissertation's source data allows examination of exogenous variables that may affect the main analysis. They may add nuance to each national innovation system's patentees' character and placement within the group of inventors who created a patentable invention that was used in an invention. Nevertheless, herein, the specific characteristics of individual co-patentees within patent-level testing are assessed with their exogenous characteristics aggregated into the generalized difference of means analysis. Aggregating participants for a generalized analysis ensures that no artificial distortions occur from the differential application of exogenous variables' effects.

Testing national innovation system effects is straightforward. A Japan-US comparison by difference of means is undertaken. Japan's and America's national innovation systems' results for patentees whose inventive group includes an academic component uses the difference of means test. Japan's pre-Industrial Revitalization Special Law proportion of academic co-patentees within individual patents is compared with America's under pre-Patent and Trademark Law Amendments Act conditions (see Tables 8a and 8b below). Table 8b shows that the means contrast. In Tables 9a and 9b another outcome is shown. Comparison of performance of academic researchers in

innovations' patents after each country's Bayh-Dole law came into being shows converging means (see Tables 9a and 9b below).

Table 8a: National Innovation Systems: Japan-US Comparison Pre-Bayh-Dole/Industrial Revitalization Law: Proportion of Public Inventors

Group Statistics

	Patent from Japan or US	N	Mean	Std. Deviation	Std. Error Mean
PctPubPatees	0	47	.9748	.45698	.06666
	1	74	.5973	.38034	.04421

Table 8b: National Innovation Systems: Japan-US Comparison Pre-Bayh-Dole/Industrial Revitalization Law: Proportion of Public Inventors

	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference
PctPubPateesEqual variances assumed	4.916	119	.000	.37745	.07678

Table 9a: National Innovation Systems: Japan-US Comparison Post-Bayh-Dole/Industrial Revitalization Law: Proportion of Public Inventors

Group Statistics

	Patent from Japan or US	N	Mean	Std. Deviation	Std. Error Mean
PctPubPatees	0	733	.6857	.43321	.01600
	1	38	.5897	.34261	.05558

Table 9b: National Innovation Systems: Japan-US Comparison Post-Bayh-Dole/Industrial Revitalization Law: Proportion of Public Inventors

	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference
PctPubPateesEqual variances assumed	1.345	769	.179	.09606	.07142

In conclusion, these results state whether patterns of academic co-patenting in Japan and the United States were similar in each of the two timeframes. Contrasting US results prior to Bayh-Dole with Japan's prior to the Industrial Revitalization Law shows that the test for significance names the two means distinct. Comparing their results after each country's policy change shows that the two had converged. This change is explained and discussed in the Results section that follows.

5.5 Bayh-Dole Effect

The final step answers this dissertation's broadly and narrowly defined research questions and explicitly answers to the hypothesis. How do rule changes evolve innovation practices? Does co-patentee networks' composition indicate that Japan's academics' practice of transferring intellectual capital to drug commercializers was changed by Bayh-Dole? Hypothetically, pharmaceutical industry commercialization data (from the United States Federal Drug Administration's Orange Book of Approved Drug Products with Therapeutic Equivalency Evaluations with augmentation from United States Patent and Trademark Office and academic and professional media) show network indicators (academics' participation among each patent's co-patentees and assignees in an

environment of speedy innovation) of Japan's academics' (compared to America's academics) value-adding practices from their intellectual capital (when Japan's academics choose to divest their intellectual seed(s) and consultations founding a patent to a commercializing firm) demonstrate that introduction of Bayh-Dole-type (Japan's Industry Revitalization Law and America's Patent and Trademark Law Amendments Act) administration to Japan's national innovation system results in no detectible change in pattern of network dynamics that constitute a value-adding practice. Both this present pre-/post- time series and the previous cross-national cross-sectional count are tested by Student's t-test for a difference of means analysis. Comparisons are, thus, made temporally here and cross-sectionally before. Analyses are as follows:

Table 10a: National Innovation Systems: US Before-After Bayh-Dole: Proportion of Public Inventors

Group Statistics

	Patent date before or after the country's Bayh-Dole act started	N	Mean	Std. Deviation	Std. Error Mean
PctPubPatees	0	47	.9748	.45698	.06666
	1	733	.6857	.43321	.01600

Table 10b: National Innovation Systems: US Before-After Bayh-Dole: Proportion of Public Inventors

	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference
PctPubPateesEqual variances assumed	4.420	778	.000	.28907	.06540

Table 11a: National Innovation Systems: Japan Before-After Industrial Revitalization Law: Proportion of Public Inventors

Group Statistics

	Patent date before or after the country's Bayh-Dole act started	N	Mean	Std. Deviation	Std. Error Mean
PctPubPatees	0	74	.5973	.38034	.04421
	1	38	.5897	.34261	.05558

Table 11b: National Innovation Systems: Japan Before-After Industrial Revitalization Law: Proportion of Public Inventors

		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference
PctPubPatees	Equal variances assumed	.104	110	.917	.00767	.07346

In conclusion, these data show that inventive-innovative behavior by academic researchers before and after each country's Bayh-Dole type law came into effect differed from one another. In the United States, the originator of Bayh-Dole type legislation and policy, data analysis shows that academics now integrate with industry more concertedly than in the past. Japan's experience has been different. Despite its fast-follower position, comparison of pre- and post-Industrial Revitalization Law commercializing behavior appears to have resulted in no greater proportion of academic involvement in the inventive-innovative process. Given the differences in p-value scores, the difference between uptake in Japan and the US is remarkably contrastive.

Before moving on, limitations of Bayh-Dole comparison to Japan's situation demands discussion. As has been well-documented in legacy literatures addressing Japan's experience with its Bayh-Dole

type legislation, Japan's Industry Revitalization Special Law was derived from the United States' Patent and Trademark Amendments Act, which goes by the popular name of Bayh-Dole. Given that Japan's change to a Bayh-Dole approach is recent at more or less ten years in practice, even that scholarly research that has addressed Japan's experience under the new legal regime principally asserts continuance of pre-Bayh-Dole themes onto the new period. This is not surprising given that few years of hard data are available. Researchers are, thus, in large part constrained to checking questionnaires. As mentioned in each section above, this dissertation's research aims to avoid reliance on assessments tinged with qualitative measures, as are questionnaires. This dissertation aims to add a strictly quantitative analysis to the discussion.

Previous literatures tend to be fairly scathing toward Japan's results under its Bayh-Dole. Kneller is the most informative and current assessor of Japan's academic innovation following its transition to a Bayh-Dole format. His research approaches are substantially limited to interviews and questionnaires that ask impressions of changes, but also include some more strictly quantitative assessment that counts patents and refers to citations and also a case study description of activities at the University of Tokyo. He strongly identifies that Japan's system is new, so acknowledges the limitations of his conclusions. This dissertation also labors under the weight of Japan's Industrial Revitalization Special Law's newness, which has resulted in Japan's post-Bayh-Dole source data being low, but mostly sufficient for the analyses done herein. Another important researcher made

notable based on his conclusions being less pessimistic than Kneller's. Florida worked extensively with Fumio Kodama and Lewis Branscomb early in his academic career and carries forth their optimism now that their publishing in this area has been largely extinguished. Japan's adoption of Bayh-Dole after many other countries has also made it a less intriguing target for scholarly research on the effects of that legislation's impacts, so where Mowery, Sampat, Hall, and Henderson did discuss Japan's situation, it tended to have been during the time when Japan was implementing the policy. Their insights are, therefore, more fully reflections on the process of implementation and legacies from before 1998.

Kneller's view of Japan's performance as an innovator is that it underachieves. He suggests, as mentioned in the section on legacy literatures, that the lack of broad-definition academic entrepreneurship and entrepreneurialism in general in Japan has led to Japan receiving poor results from its investment in changing to a Bayh-Dole approach. He argues that the lack of champions to nurture innovations through their advanced stages of research and development and into sales and marketing hobbles Japan's ability to take advantage of the opportunities that the Industrial Revitalization Special Law provides (Kneller, October 2008)(Kneller, 2010). My own informal discussions with TLO agents and representatives confirms Kneller's pessimistic finding as they typically referred to Japan as a laggard in academic innovating. Further, Kneller suggests that Japan's corporate culture tends to avoid the trappings of open innovation that would allow an

alternate route to completion of research to the product development phase (Kneller, November 2010). All in all, Kneller reflects the concerns expressed by well-known researchers like Mowery who criticized Japan's industry-academia relationships, even though their views were formed before the new law had even come into effect.

Florida and Kodama's writings suggest a more positive appraisal. In their writings, Japan's technical edge arises from the cultural characteristics of group-think. The monolithicity of Japan's population works well to collectively innovate (Branscomb *et al*, 1993) is seen as a source of enfranchisement that liberates Japanese workers' innovative productivity. Florida's principal research focus is creativity as embedded in the marketplace. Thus, in early writing with Branscomb and Kodama, he asserted Japan's creative competence as being further liberated by the Industrial Revitalization Special Law's extrinsic and express motivators (Branscomb *et al*, 1999). Nevertheless, in his more recent works, he specifically identifies the worldwide spread of Bayh-Dole type administrations as a precursor to global creativity competition that he characterizes as creativity wars (Florida, 2012). Japan's Industrial Revitalization Special Law is seen as an expression of that creativity competition between national innovation systems.

Thus it is that this research's limitations are addressed in legacy literature, though not robustly. Though Japan's Industrial Revitalization Special Law and the other laws that brought Japan competitiveness in creative competence, legal and cultural differences still strongly divide Japan's

performance from that of other countries. Japan's Bayh-Dole does not explicitly encourage small firms over large, so it acts as a more strict market mechanism than does the US law. Japan's legacy academic and business cultures augment that legal dissimilarity. Japan's academic researchers have long retained an opaque, but functional and flexible academia-industry complementarity. The IRL merely makes those relationships less opaque and susceptible to market failure. This research is not limited by assessing Japan's and America's respective Bayh-Dole systems, because they are almost the same. Culture pushes Japan's and America's responses apart, but the similarities of the laws is a given.

Limitations in applying US-sourced depictions of Japan's innovation processes cause greater concern. That point is fully addressed in the subsection on descriptives. To return to that point, though Japan's drug development firms may produce new medical devices and drugs that do not appear in US documentation because of legal limits, this dissertation confines its examination to innovations with global reach and a commonality of intellectual property rules. Thus, though Japanese source data is applicable, US data actually provides a more accurate portrait of Japan's scope of innovation and it also has a longer history, so makes older data available. Therefore, this dissertation's research initiatives are liberated, not limited, by using US sources, such as the USFDA's Orange Book and USPTO's patent files, and English-language sourced identifications of patentees' affiliation—academic or not. Only using US data gives better information for better

results.

Also noteworthy as a limitation to the universality of this dissertation's findings is the role of cultural change shown in both Japan and the United States of America with regard to open innovation. While Japan's firms retained a strong bias against inventions and developments that were "not invented here" until the late 1990s and large US firms retained an in-house discrimination until about the same time, pharmaceutical industry interaction with and benefit from relations with practicing academic researchers appears to have led the transition to open innovation and so adopted its benefits earlier. In the US, the dismantling of polymorphic conglomerates into focused smaller corporations saw the role of its famous private research campuses, like those of Xerox, IBM, and Du Pont, on the outside of parts of their former firms. A new ethos arose that saw companies' research and development sections become porous as they became more selective of targeted research projects. Those that were rejected for further development were allowed to depart the firm as revenue generators. Simultaneously, trends toward outsourcing found corporate R&D relatively open to technologies developed elsewhere being brought in for fitting and utilization in and on projects in process. This fluidity was particularly welcome in the pharmaceuticals industry where overhead is high and the product pipeline is long and expensive to maintain. Japan's relatively smaller firms at play in the pharmaceutical market also became more willing to import technologies in order to compete, but were already well-positioned in the Japanese context to take advantage of

the industry-academia-government nexus. Japan had long been a leader in government meddling in the market in order to develop consensus of action and market coordination in the name of efficiency and effective exploitation of markets. Further, Japan's academic culture had accommodated several aspects of the country's post-war liberalization to effect widespread collaborative research and, given the long and costly timelines common in drug development, pharmaceutical firms were well-embedded among academics. Open innovation was well-entrenched for Japan's drug developers by the early 1990s, ahead of other industries and at a similar time as when the larger US-based firms grew open. Thus, this dissertation's findings must be taken carefully in order to account for that exogenous factor's impact on academic participation.

5.6 Conclusion

These descriptive statistics provided three analyses. Approval level and patent level data was used for categories that showcased exogenous effects. Next, each of national innovation system level effects and Bayh-Dole timed effects were compared using difference of means analysis of co-patentee level input into patent-level analysis. Comparison between the national innovation system results and those of the final Bayh-Dole Effects analysis answer this dissertation's hypothesis.

Beginning with proof of the source data's validity through the descriptives section, then descriptive statistics for examining trends and differences of means, this analysis section has shown the

workings of this dissertation's data management and analysis in order to gain insights into network indicators of Japan's academic value-adding practices from their intellectual capital relative to America's.

6 Results

6.1 Introduction

The results of the above derived analyses provide three ranges of data. The first uses descriptives to show how valid is the source data for answering this dissertation's hypothesis. The second analysis uses difference of means testing to discern whether Japan's academics' practice of transferring intellectual capital to drug commercializers was changed by the Industrial Revitalization Law to reflect US results from Bayh-Dole.

6.2 Descriptives

Description of the source data verifies the parameters of its usefulness in answering this dissertation's hypothesis. Simply, because the source data is a whole population, it is liberated from issues of sampling error. Its skewness and kurtosis, for example, are legitimate, because they represent the real data, not a poor sampling. As such, results show that the total populations are sufficiently numerous to be confidently used as a sample for extrapolating future outcomes in addition to commenting on its actual timeframe.

6.3 Descriptive Statistics

Results from three types of descriptive statistics are presented here, each conforming to a level of analysis. Drug approvals analysis provides a preliminary overview of the role of USFDA approved drugs. That for patents tracks several variables that contribute or are exogenous to calculations that would answer this dissertation's hypothesis. Finally, co-patentee calculations say how inventors within national innovation systems individually choose to team up to advance their research and development activities. Each step builds toward both a richer understanding of the background variables and answers whether this dissertation's null hypothesis is supported.

6.4 National Innovation System Effects

Testing national innovation system effects is simple. The data is divided between prior to and following each national innovation system's respective Bayh-Dole moment. A Japan-US comparison by difference of means is undertaken separately for pre- and post-Bayh-Dole data to determine the comparability of the two countries' results under each of the two conditions.

In the null phase, when there was no Bayh-Dole type legislation governing the country's academics, it is anticipated that cultural, administrative, and historical distinctivenesses would make the means of each country significantly different. That is borne out by the data. Japan's and America's means show no significance at all (see figure 9b). The 2-tailed significance is zero. They do not share normality. Given that the Industrial Revitalization Special Law was meant to usher in the

kinds of feats believed achieved by the US under Bayh-Dole for Japan, one would anticipate that the means would show indistinctive difference either at present or sometime in the future. That has already occurred (see Table 9a), according to this data, though, as the Conclusion section will show, there is more to this story. In that table, the significance scores can be seen to have exceeded the 0.05 boundary rate. With a score of 0.17, that the two means are different cannot be accepted.

In conclusion, these results state whether patterns of academic co-patenting in Japan and the United States were similar in each of the two timeframes. Contrasting US results prior to Bayh-Dole with Japan's prior to the Industrial Revitalization Law shows that the p-test for significance names the two means distinct. Comparing their results after each country's policy change showed that the two had converged.

6.5 Bayh-Dole Effect

How do rule changes evolve innovation practices? Does co-patentee networks' composition indicate that Japan's academics' practice of transferring intellectual capital to drug commercializers was changed by Bayh-Dole?

The US appears to have changed since before the Bayh-Dole Act came into force. Table 10b shows that its earlier results varied absolutely from its later ones (see Table 10b). It does not define how those changes might have looked, but, given understanding of Japan's academic invention and innovation behavior, the previous section shows that the US appears to have taken on the level of

integration with commercial research that Japan's academics have long enjoyed. In this way, these results say more about the United States' changes than Japans, which is interesting in itself.

Japan's results across the Industrial Revitalization Special Law divide offer up a very different story. Its significance scores in these t-tests are, depending on assumed variance, clearly showing consistency with a number of 0.917 (see Table 11b). Concluding on this awaits for the concluding section of this dissertation.

In conclusion, these data show that inventive-innovative behavior by academic researchers before and after each country's Bayh-Dole type law came into effect was different. In the United States, the originator of Bayh-Dole type legislation and policy, data analysis shows that academics now integrate with industry more concertedly than in the past. Japan's experience has been different. Despite its fast-follower position, comparison of pre- and post-Industrial Revitalization Law commercializing behavior appears to have resulted in no greater proportion of academic involvement in the inventive-innovative process. Given the differences in p-value scores, the difference between uptake in Japan and the US is remarkably contrastive.

6.6 Conclusion

Between descriptives and descriptive statistics, the Results section of this dissertation clarifies the key outcomes from the Analysis section of this thesis. Those two sections show the validity and content of the raw source data and then assess it at three levels of analysis. The end result is a clear

answer for this dissertation's hypothesis.

7. Discussion

7.1 Purpose of this Discussion

Results suggest that Japan's academic researchers' value-adding practices were quantitatively unaffected by Bayh-Dole, but may have been affected qualitatively. Due to exigencies in the source data and analysis and to exogenous variables that may be at play, these outcomes demand further non-statistical consideration to put them in context. That is the purpose of this Discussion section.

7.2 Structure of this Discussion

After the purpose outlined above, this discussion examines source data and the theoretical framework of analysis. These encapsulate this dissertation's contributing data, the statistics that drive its analysis, and the result of data analysis. Patterns and exceptions in the observations and generalizations among the results, the rival contentions of the mechanisms that may be underlying these patterns, agreement and disagreement with major contributors' research findings, rival answers to the question of how policy change affects academics' innovation practices, and value of this dissertation's findings within the context of alternative hypotheses generated by legacy literature. Thus, the main components of this dissertation—data, analysis and conclusions—are discussed more holistically than elsewhere in this report.

7.3 Discussion of Source Data

By viewing results in Japan and America pre- and post-Bayh-Dole, this dissertation sought to verify if and how Japan's national innovation system's academics' value-adding practices evolved under the influence of Bayh-Dole-type legislation and its administration. Unbiased verification is achieved by employing the most temporally comprehensive, transnationally comparable, accurate to definitions of innovation, invention, and affiliation, and relevant to the policy change source-data available. This meant employing (a) pharmaceuticals (which Japan and the United States share the same markets, generate most TLO/TTO revenue, and are fully, publicly disclosed for purposes of medical and legal scrutiny) (b) innovations' (all USFDA-CDER approved drugs (approval being a pre-requisite for marketing pharmaceuticals in the US, the world's biggest drug market)) (c) inventions' inventors (drugs' USPTO patents' date and patentee and assignee nationality) by (d) inventors' and assignees' proprietary contributions during patents' inventive process (patentees' affiliations—academic or not—as stipulated by academic and professional publications). Thus, a dataset built from these three contributors allows changes over time in the propensity for academics to participate in networked inventive research that leads to commercialized innovations to be analyzed.

Rival quantitative data sourcing approaches to measuring network effects in innovation systems principally derive from patent-sourced data to analyze using either geographic distribution or

citations. Further, those citations may, as shown in patent content, cite both or either of prior art patents or journal articles. One further highly uncommon type of network analysis based approach tracks individuals through their various journal and patent teams so that individuals represent nodes with linkages to other inventors and researchers. The rival network analysis capabilities offered by patents, citations and geography data each explain the spillover, diffusion and linkages.

Assessment by the last method demonstrates networking in its purest form. The number of links extending from any person's or institution's node explicitly quantifies how many connections are present. Counting the number and strength of said links is where analysis occurs. However, any meaning beyond proclivity to generate knowledge is only determined by linking the complexities of network nodes and links with overlapping data content and, in that way, provides conclusions on network effects achieving results for whatever content overlaps it (Audretsch and Feldman, 1996)(Trajtenberg, 1990). The consequence is that this data source merely offers a matrix of people or institutions, so fails to offer a nuanced view of network effects—nuanced by the character of the connections.

Citations, the second noted rival method of quantitative data gathering operates under the assumption that prior art patents and published journal articles represent effects other than simple knowledge dispersal. In showing knowledge flows, counting citations is counting knowledge as it transfers from one entity to another—giving credit where credit is due—but extrapolating citations

to valuation of intellectual capital, to invention, or to innovation is to suggest that patents are the end product, not a phase in the innovative process. Having said that, a considerable field of research is developing that appears to show that knowledge flows are linked to entrepreneurship and innovation (Hall *et al*, September 2007)(Hall *et al*, October 2001)(Mowery *et al*, 2004). It is concluded that, counting citations expresses characteristics of knowledge flows very well, but extension of conclusions to innovation, entrepreneurship, or valuation require a higher burden of proof than data sources that derive from those three directly.

Geography offers another form of content. Construction of nodes and linkages that accrue to geographical proximity is largely limited to assessments of knowledge spillovers, though, to a lesser extent, notions of national innovation systems also use this method, but only bluntly. In this case, clustering of innovative firms, institutions, and, to a much lesser extent, individuals is rallied to ascertain macroeconomic effects lying outside the undiscriminating method of citations. Geography allows nuance by distance to account for complexities in spillover results. A further component of the study of the geography of clusters is the determination of which firms or institutions act as the hub around which a cluster forms. Anchor-tenant theory arises from this approach. Curiously, Nooteboom's later work applies a similar, but non-geographic, method for assessment when he proposed cognitive distance for understanding patterns of innovativeness in firms. He finds that participants in networks create knowledge differently depending on how

similar the firms' knowledge bases, experiences, and technological capabilities are (Nooteboom, 1998). Therefore, by physical or cognitive distance, innovation receives a nuanced weighting of various relationships.

Additionally, as noted in several locations in this dissertation, the data source provides meaningful longitudinal information. Chronology can be discerned by any of the several dates provided in the USFDA-CDER source and USPTO patents in a timeframe extending from 1965 to 2012. It would be silly to assume that Bayh-Dole effects would be the only feature to be expressed over that period. Economic vacillations and shocks in addition to exogenous evolutions in administrative practices and market characteristics resulting from scarcities, legal changes or significant changes in how potential innovators, funders, administrators and customers view the then-present and future all can be anticipated to have had impacts. What was the result of firms downsizing, off-shoring, and embracing open innovation? These data sources cannot say. What can be suggested is that, insofar as academia's government funded research is a factor expressed within the national innovation system, the globalization of pharmaceutical industry research would not undermine Bayh-Dole analysis. Though they may be globally-minded and integrated, academics' institutional and market incentives accrue from law and funding, which are, under Bayh-Dole, national in origin and effect. Separating out these impacts from only these data sources is impossible, so diminishes the significance of conclusions arising from their statistical analysis.

Bayh-Dole, however, appears responsible for negative effect that this data could analyze, but did not due to its constraint to a broad analysis. Bayh-Dole gives incentives for commercializing academic research and that appears to have led to a "tragedy of the commons" scenario. Tragedy of the commons received comment in the review of legacy literature where that view was contrasted with the idea that Bayh-Dole is the golden goose of technology transfer. Bayh-Dole appears to be a golden goose, but its incentivization of research appears to lead to greater restriction and unwillingness to share learnings garnered from government-funded research. This is an ethical travesty against the Ivory Tower and taxpayers, but it also undermines the diffusion of knowledge that underpins academia's role in the diffusion of innovative ideas. Surely, it is a complex and nuanced issue. Arguably, firms freely benefitted from taxpayers' funding in past, because the information was freely available, but lack of proprietary exclusivity in face of the low cost of reverse engineering and work-arounds provides a disincentive to finish to commercialization the results of public research. Bayh-Dole was meant to address this shortcoming, but resulted in the opposite shortcoming—a tragedy of the commons situation. This is believed to have occurred in Japan, as in America, though both appear to have coincided, not with each country's Bayh-Dole law but with the period when collaborative research (defined as inclusive of both collaborative and sponsored research) grew dramatically—in the 1990s (NISTEP, 2010)(MEXT, 2013). This will receive additional comment in the following Theoretical Framework subsection in connection with open

innovation, but here, related to source data, it suggests that academics' co-patentee groups would shrink as incentives to withhold dissemination of information grew. This data can inform on group size and specify for academic participation, but, as the impact of tragedy of the commons is unclear, it was not included herein. Legacy literature principally focuses on the issue as one of ethics. Where it does receive an economic or academic question, prior research (Montobbio, 2009)(Hall *et al*, September 2007) suggests that both are impacted positively. Academic research is richer and more diverse and spillovers in the vicinities of universities are increasing local economies' diversity, integration and productivity for the inclusion of non-academic research activities into academia's realm. Therefore, the data may also be able to show if academic drug innovators are suffering from exclusivities generated by a Bayh-Dole-sourced Tragedy of the Commons.

Thus, three rival quantitative data sources utilized for quantitative analysis are presented here. Each offers an area of strength, be they knowledge spillover, knowledge dissemination, or knowledge linkages. In each of the three cases, studies are most often cross-sectional, though even the small proportion of longitudinal data tested among patent citations offers a large body of research, since citation analyses have the overwhelming share of such research. Finally, all depend on cross-referencing network findings with connected information in order that sophisticated conclusions can be drawn. In these respects, the data offered herein adheres most nearly to Nooteboom's cognitive distance framework, but using academic co-patentees rather than firms'

characters and strength of their supplier-producer relationship.

7.4 Discussion of Theoretical Framework

As noted in the introduction, review of legacy literature, and analysis sections above, "fail fast" is coined as the analytical backbone of this study as it arises from network analysis. Nooteboom's assesses innovative speed by network analysis of integration between suppliers and the innovating firm. Speed is a constant in innovation. This dissertation's theoretical framework replaces Nooteboom's suppliers with inventors and assesses innovations quantitatively rather than through firms' reportage. Speedy innovation processes maximize value. However, where the innovation process laps into academia it lapses into a less speed-driven work ethic, since, for academic researchers, academic rigor and quality of research trumps quantity. By network analysis, the academicness of the inventive community of USPTO co-patentees mates with Nooteboom's framework, whereas innovation network research tends to tally geography or patent citations that say little about academics' value-adding practice. Herein, speed of academics selling their intellectual property rights is identified by the composition of innovations' patents' co-patentees and that act of selling is the value-adding proposition. Their networking for speed is a value-adding practice. Speed and value adding theory is stated below.

This research tests Japan's academic researchers' value-adding practices via network analysis of the evolving ratio of academics among pharmaceutical innovations' inventors as Japan and America

imposed their respective Bayh-Dole type law. Academic proportion among co-patentees shows speed. Since universities do not retail drugs, their knowhow and inventive seeds are transferred to firms that develop, market, and sell them. Pharmaceutical firms are time sensitive. Thus, early transfer of academics' IP-rights has firms add their researchers to complete the inventions. More academics shows IP was retained longer, fewer shorter. Moreover, academics' speed adds value differently than commercial researchers'. Logically, more research reduces risk. Reduced risk improves a seed's value by reducing its chance of failure. Thus, it adds value for academics that retain seeds longer. Therefore, academicness of co-patentee networks tell if Japan's academics grew market-oriented after the country's Industrial Revitalization Special Law and three supporting laws were enacted.

Rival analyses to Nooteboom's focus on the impetus of speed include the suggestion that evolving market conditions rather than Bayh-Dole effects are causing the results found herein. Specifically, the rise of open innovation, of outsourcing, off-shoring, the breaking up of formerly diversified conglomerates and investment markets' disenthusia for risk occur at about the same time as the Patent and Trademark Amendments Act in the United States and later, if at all, in Japan. Transaction Cost economics is the method most often employed and Nooteboom's theories arise from it as well. Consequently, this dissertation's analysis, which is a derivative of that used by Nooteboom, follows that same approach.

The Anchor-Tenant hypothesis (Cockburn and Agrawal, 2002) noted above may offer additional insights, but, for the source data used herein, identification of differential between co-patentees in order to suggest which is the leader and which the followers is not provided. Suggestion that the academic in each group of inventors is the anchor would be an unsupported assumption. While problematic for this dissertation's source data, the Anchor-Tenant hypothesis would suggest that the results attained in the data analyzed herein resulted from anchor inventors who engineer the co-patentee group to maximize potential for value generation. Given that academic researchers tend to produce more radical intellectual seeds than is typical among non-academics, they could be assumed to be that anchor, but the only way to actually determine this would be to access research records or track TTO technology transfers. Doing so would require new data entries. Further, Anchor-Tenant would conclude that test results reported herein would show the effect as of enclosure as per the Tragedy of the Commons, but not necessarily where the size or proportion of non-academic co-patentees would decrease, but would show increasing exclusion of co-patentees from various institutions. Innovations would have come to limit co-inventors only to those within the anchor academic's institution and that institution to which his or her TLO or TTO disseminates it.

Embeddedness offers another view. Applying Uzzi's broader framework to drug development assesses the extent to which a particular academic inventor finds him- or herself affixed with a given

inventive community or firm (Powell, 1990)(Powell, White, Owen-Smith and Moody, 2004) is an appealing consideration. Were tested academic researchers to alter their associations following Bayh-Dole, it would indicate that an effect were present. This would require the testing of only serial innovators (Colyvas and Powell, 2007), which is a miniscule number that would certainly not reach a number of cases sufficient for statistical significance in Japanese results. Thus, drug innovations alone could not be used and the source data would need to be expanded, perhaps by using patents not directly connected to innovations. While including them would undermine the credibility of limiting source data on innovations only to proven innovations, it could provide interesting results that could provisionally be applied to innovations.

Increasing synthesizing as a result of Bayh-Dole is another alternative perspective. Nonaka, Takeuchi, and Toyama's co-authorship suggests that changes in incentives for academic researchers in their working with others is a primary motivator and generator of successful new product innovations (Takeuchi and Nonaka, 1986)(Nonaka and Toyama, July 2003). Their conclusion would follow the apprehension that integrative open innovation is the emergent form of inter-researcher nexus formation. In this case, post-Bayh-Dole transitions should lead to greater diversity within co-patentee groups. This is the opposite conclusion of that of Embeddedness.

Focus on mitigation of risk provides a further contrast to network analysis as applied herein. Risk is implicit in research and more so for new molecular entities than incremental development of

product, but increased sophistication of capital markets has added pressure on firms to perform on ever shortening timelines (Philipson, Mechoulan, and Jena, 2006). For research and development activities, it is known to have resulted in pharmaceutical firms accommodating academia sourced research to supplement and augment their own labs(Stern, Porter, and Furman, 2000)(Hall, 2004) (Hall, 2007). In this way, efficiency has driven open innovation initiatives in drug development. Thus, this dissertation's results are reinterpreted by this analytical framework to suggest that pull from commercial enterprises is drawing academics into those firms' research initiatives as a method for them to reduce costs associated with risk. However, this dissertation's conclusions do not preclude that corporations' pull effects may be present in the data, but, rather, assert that those results would occur as noise in its source data and are likely to be affected by Bayh-Dole anyhow.

Finally, Principal-Agent theory provides a contrastive alternative based on the notion that universities, as academic researchers' employers, determine outcomes, not the researchers themselves. The logic of this is indisputable. Employers auger demands on their employees, but academics are knowledge workers more capable of engineering hold-up that undermines their principal's authority and control over them in the largely voluntary environment that is innovation research (Schankerman and Lach, 2003). Others dispute this to suggest that commercialization counterproductively incentivizes revenue-generation research over longer-term outcomes (Jensen and M. Thursby, 2004) (M. Thursby, J. Thursby, and Dechenaux, 2005). Though this dissertation's

source data cannot definitively stipulate the extent to which principals have exercised authority and control over their academic faculty, effectively making the latter pawns of the former, following this logic, the whole basis of this dissertation's data, analysis and conclusions would be suspect. However, that analysis of that data suggests that authors of legacy literature skeptical of university administrations' power to impose authority in the inventive process are in error. Were their perspective persuasive, academic co-patentees would be overwhelmingly accompanied by academic institutions assigneeship or co-assigneeship. Though a significant minority of innovations' patents show this parallel, a more significant majority do not.

Concluding on the limits of this dissertation's analysis and scrutiny of rival hypotheses, this subsection has noted several frameworks that have extensive and diverse authorship in the legacy literature and do draw into question the findings and meaning of those findings based on those rival hypotheses.

7.5 Conclusion of Discussion

In conclusion, Results suggest that Japan's academic researchers' value-adding practices were quantitatively unaffected by Bayh-Dole, but may have been affected qualitatively. However, account must be given to alternative appraisals, particularly arising from exigencies in the source data and analysis and to exogenous variables that may be at play. The above discussion showed some of the other perspectives to which allusion was made in earlier sections of this dissertation,

especially in the section reviewing legacy literature. Overall, the weight of different source data and analytical frameworks accounts for much of the diversity of opinion shown in this area of study: academic innovation processes, specifically in drug discovery. More than contradicting one another, these varied sources and analytical approaches enrich the body of research dedicated to that topic. This dissertation's findings are offered to further add to the understanding of policy's effect on academic innovation processes.

These findings are valuable. They reinforce the already solid research findings of other suggesting of the limits of Bayh-Dole type policy administration on its intended beneficiaries and actors. That this dissertation's research utilizes a new, but highly important and highly trustworthy, data source and limits assessment to actual commercialized inventions—the definition of innovation—rather than proxies, like patents or publications, or approximations, like answers to questionnaires, or case studies, which hinder generalization due to their topical specificity. This dissertation's reliance on blind quantitative data on innovation in drug development, which is academia's top revenue generator, ensures its relevance and value to both policymakers and agents of technology transfer. That its outcomes fundamentally align with Mowery's criticism that introduction of Bayh-Dole has proven to be of little value to academia is particularly interesting as its completely unrelated source data (USFDA approved drugs) and theoretical framework for analysis (network analysis) do, nevertheless, back up his assertion, at least in relation to the results of Japan's academics'

value-adding practices from their intellectual capital. The success of policy change clearly appears highly dependent on the nature of the relevant national innovation system's cultural, historical and administrative legacies despite the unifying impact of globalization, since dispersion of intellectual capital to further economic development appears to have already been highly productive in Japan prior to introduction of the Industrial Revitalization Special Law.

7 Conclusions

7.1 Introduction

This Conclusion section links research results with background commentary provided in the literature review in order to make meaning of those results. The hypothetical question being answered in this dissertation is whether Japan's and America's academics' intellectual capital commercialization practice changed as a result of Bayh-Dole type legislation. The USFDA's CDER's Orange Book provides this research with a legitimate and extremely thoroughly documented and uniformly sanctioned population of innovations from throughout the world. Those innovation's patents' inventors and assignees time and location information is provided by the USPTO. Finally, published and agency information is available through scholarly and industry publications to determine patentee's employment affiliation at the time of patenting. Thus, relating innovations' inventors' academic character within inventive teams by time and location allows this dissertation's analysis to use the academic composition of patents' teams to explain their networking

practices as a proxy for academic inventors' retaining their inventive seeds more robustly into the research and development process.

7.2 Concluding on Descriptives

Adjusting for the scale of each economy and the size of each national innovation system's drug markets, Japan and the United States of America show great similarity in their representation within the pharmaceutical products development and invention marketplace.

As might be expected, given that Japan's and America's technological expertise, material sophistication, advanced education, and presence of global pharmaceutical commercializing firms, research and development speeds per patent are very similar. Japan's slight lag behind the US in speed is so small that it is likely caused by administrative issues of priority filing of patents and trans-national clinical trials as much or more than any result of actual researching speeds. Finally, the difference between Japan's and the US's relationship between public patenteeship and academic assigneeship is small. However similar are the outcomes, the causes are likely quite different between the two, since America's contract-based legal culture, mature licensing system and greater focus on short-term financial results encourage early licensure of inventive seeds while Japan's legacy relational associations between pharmaceutical firms and academic researchers means that both cultures may be showing similar agency theory results from different sources. Nonetheless, similarity in results is undeniable in all of these cases.

The conclusion arising from this information detail is that Japan and America are highly comparable. As Kneller (Kneller, 2008) and also Kodama, Branscomb and Florida (Branscomb et al, 1999) note, their research capabilities are similarly advanced. Their access to commercializing firms is complementary. Both are about equally dedicated academicians. Though the cultural and practical underpinnings of these characteristics may have different roots, as Kodama suggests (Kodama, 1995) and Kneller alludes (Kneller, 2008), numerical results show that, though the path may not be identical, the destination is barely distinguishable between them. Thus, both countries' national innovation systems' descriptives suggest high comparability for analytical testing.

7.3 Concluding on Hypothesis Testing Analyses

The final analyses address the hypothesis on two axes: comparison of national innovation system results and by contrast of pre- and post-Bayh-Dole Act/Industrial Revitalization Law effects. The findings apparent self-contradictory character does, in fact, illuminate a narrow determination of conclusions. Results show four comparisons.

The first comparison is between those countries' performance from before each national innovation system's Bayh-Dole law came into effect. Japan's and America's proportions of academic co-patenteeship showed that the countries' norms, their means, were confidently different. That this was the case appears uncontested by the legacy literature surveyed, most notably from Kneller (Kneller, 2008) and Kodama (Branscomb, Kodama, and Florida, 1998). Kodama specifically

identifies this characteristic as culturally derived and intrinsic. Kneller views it more as a managerial issue and relatively unconstrained. Nevertheless, the point is that, whether for cultural or historic administrative reasons, Japan's Ivory Tower ethos allowed considerable collaboration with industry while the American version appears to have resisted blurring of the public-private divide. Whatever the actual specifics underlying the difference, a definite difference has been identified in this quantitative data showing that Japan's academics behaved more collaboratively with industry from a pre-Industrial Revitalization Law period than did America's academics pre-Bayh-Dole.

After Bayh-Dole and Industrial Revitalization Law findings are starkly different. Japan's and America's norms had become statistically irrelevant. The initial suspicion of this is that the effect of Japan's Industrial Revitalization Law was successful. That Japan's academics' had accommodated the new system in a quick "fast follower" style that made them behave as entrepreneurially or at least opportunistically as those in the US. On this specific issue, legacy literature is remarkably quiet regarding Japan-US comparison. Kneller's views stop at his judgment that Japan is not competing well, so debate on the level of success is surprisingly mute. Certainly, it may be true that Japan quickly caught up and changed its behavior. It may also be that the earlier suggestion that Japan and the US have the same destination, but use different practical routes to get there may be occurring in this case also. To answer which of these is most accurate,

this dissertation's conclusions turn to the view of how academics' inventive and innovative behavior changed internally. This is the within-country across the Bayh-Dole/Industrial Revitalization Law boundary difference of means analysis and its conclusions are presented next.

America's academics performance in networking their inventive and innovative processes shows a clear difference between prior to and following the Bayh-Dole Act coming into effect. Scholarly criticism very strongly contests that this has occurred and their data sources support their conclusions. The data source used herein, which attests to inventive behavior in the creation of innovations and is a more selective and pertinent to success than are examinations of patenting and citations and is less subject to attribution errors inherent in qualitative analyses, shows that US-based academic researchers' behavior has changed. It appears that America's academics became more entrepreneurial, both in the general definition of the Thursbys, of Mowery and Sampat, and Bronwyn Hall (entrepreneurial as in enterprising for profit), and in the narrower definition of Kenney and Patton, Azoulay, and Powell (entrepreneurial as in starting new businesses). Thus, it must be accepted that, at face value, Bayh-Dole was the harbinger of the change.

Japan's Academics performance did not show America's turn. Clearly, analysis by difference of means shows that no difference developed. Given the dynamic change in the US system, the easy conclusion is that Japan's law failed to overcome path dependent behavior by its academics and the cultural norms from prior to the law being enacted were retained. Kodama suggested that this

should be true (Kodama, 1995), given his ascription that culture changes slowly and is somewhat randomly favored or disfavored by market and economic conditions. In this respect, legacy literature suggesting that market drives innovation capacity (Azoulay, Ding, and Stuart, 2005)(Azoulay, Ding, and Stuart, 2006) supports Kodama's view. What appears to have occurred is that Japan's behavior changes are not registering discretely in this data. Japan's new law certainly brings a culture whereby, as mentioned above, Japan's academics enjoyed very collegial relations with industry research associates, into the light. America's academics are latecomers to this level of collegiality, but in both Japan and the US it is now legally above the board, not under the table. Thus, Japan's academics appear to have already reside where US academia has only recently ventured: the triple helix of industry-academia-government cooperation. Descriptive data presented herein provides some credence for this view, but, perversely, contradicts the aim of Japan's Bayh-Dole type law. Prior to law coming into effect, several patents had academic assignees. After, only one had a public assignee, and that was a hospital, not a university. This happened despite other factors in the cases after the 1999-2004 divide rising slightly. The numbers of cases are too small to create confident statistical analysis, but the implication is clear and somewhat substantiated by the data. Japan already arrived at America's inventive behavior before it enacted the Industrial Revitalization Law.

Thus, in answering the hypothesis' research question, did Japan's Industrial Revitalization Law change Japan's academics inventive behavior, the answer is that it did not encourage greater participation rates, as it did for America after Bayh-Dole. Further, that Japan's post-Industrial Revitalization Law performance matches America's post-Bayh-Dole, strongly concludes that Japan's law lacked the game-changing incentives underlying America's cultural need for a Bayh-Dole type act.

7.5 Conclusion

This dissertation analyzed innovations' co-patentees' affiliations data from the US pharmaceutical market to arrive at its hypothesis' conclusion. That hypothesis arises from a pair of research questions, one broad and one narrow. How do rule changes evolve innovation practices? This leads to the question of the hypothesis: does co-patentee networks' composition indicate that Japan's academics' practice of transferring intellectual capital to drug commercializers was changed by Bayh-Dole? The hypothesis is as follows:

Pharmaceutical industry commercialization data (from the United States Federal Drug Administration's Orange Book of Approved Drug Products with Therapeutic Equivalency Evaluations with augmentation from United States Patent and Trademark Office and academic and professional media) show network indicators (academics' participation among each patent's co-patentees and assignees in an environment of speedy innovation) of Japan's academics' (compared to America's academics) value-adding practices from their intellectual capital (when Japan's academics choose to divest their intellectual seed(s) and consultations founding a patent to a commercializing firm) demonstrate that introduction of Bayh-Dole-type (Japan's Industry Revitalization Law and America's Patent and Trademark Law Amendments Act) administration to Japan's national innovation system results in no detectible change in pattern of network dynamics

that constitute a value-adding practice.

Pre- and post-Bayh-Dole/Industrial Revitalization Law cross-comparisons between US and Japan academics' co-patenting networking concludes that Japan's academics' inventive capacity was not transformed by its national innovation system's policy change.

8 Further Research

This report's research findings define the trajectory of Japan's academic inventors' value-adding practices for their intellectual capital in comparison to that of the United States of America's. While informative, comparison among all the major national innovation systems would decisively define whether convergence is global or how global it is. I note that, in addition to the Japan and US data presented in this report, I have the data of all countries represented in the USFDA database's patents, so such a universal, global demonstration of national innovative capacity trajectories is possible in the future and would enhance the value of the conclusions presented in the results section of this dissertation.

Additionally, the validity of this report's foundations would be enhanced by the determination of the relationship between each country's IP balance of payments and Porter's national innovative capacity in order to verify the results of this report's first hypothesis, that Japan-based inventors get correct representation in the US measuring tools that are the USFDA Orange Book of Approved Drug Products and Therapeutic Equivalence Evaluation database and the USPTO patent database.

Another point for two further research initiatives is, firstly, to connect these results with those of

other industries for which data is less available than for pharmaceuticals as such an association would allow extrapolation of tracked pharmaceutical results to suggest what is likely happening in other areas of innovation that are able to be linked with pharmaceutical industry innovation results and, secondly, to connect other measures to these, such as remuneration and human resources, to these trajectories in order to provide vertical extrapolations of this report's results' econometrics.

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