

博士学位論文審査要旨

2013年7月25日

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：

マリン・レバース氏の研究は、産学連携による研究開発活動が、経済競争力の促進にとって重要であるという認識に立ち、産学連携による研究開発を促進する政策について分析を行うものである。特に、米国連邦政府の資金で研究開発された発明の特許権を大学等の研究者に付与することを認めたバイドール法(1980年制定)が、産学連携をどのように推進し、研究開発の成果が産業界にどのように活用されたかを明らかにすることが主要な研究テーマとなっている。さらに、日本でも1999年に産業活力再生特別措置法の第30条で定められた内容が日本版バイドール法と見なされており、この法律制定によって日本における産学連携による研究開発がどのように進展したかについても、日米比較研究を行っている。

上記の分析は、日米特許に関連した特許データを使用する必要があるため、データを探す点においても困難な作業を伴う。特に、日米間での比較を可能にするためには、同一産業等、利用可能なデータに関して多くの制約が存在している。レバース氏は、様々な検討を繰り返した後に、米国の製薬企業の特許データを用いることによって分析を行った。製薬企業の特許データを用いた理由は、日米間でほぼ同一の市場を対象にマーケティングが行われており、企業収入の大半が特許に基づく収入であり、研究開発の重要性が極めて大きな産業であること、そして特許に関する情報がほぼ完全に公開されていることにある。この特許データには、特許取得の日付、特許保有者(企業)とその国籍といった情報が含まれている。そして、最も重要な点は、データに特許保有者の所属が学術機関であるのか民間企業であるのかについての情報が含まれており、開発時における大学等の学術機関の貢献度合いが識別できることにある。これらの情報を基に、バイドール法の成立前後において、研究開発における学術機関の寄与の程度がどのように変化したかを、日米それぞれについて分析を行い、日米間でのバイドール法成立の影響に関する比較を行っている。これまでの研究開発に関する研究では、開発の地理的要因および特許利用に関して焦点が置

かれており、大学等の学術機関の役割に関しては関心が払われてきていなかった。この意味において、本博士論文は研究開発に関する研究に対して、重要な学術的貢献を行っているとは判断できよう。

分析の結果、パイプライン法成立後においても、製薬産業データからは日本における学術機関の役割がまだまだ十分に発揮されているとは言えないことが示されている。この原因等に関する詳細な研究は、今後の研究課題として残されているが、このことによって博士論文としての価値を損なうものではない。

よって、本論文は、博士（技術経営）（同志社大学）の学位を授与するにふさわしいものであると認められる。

総合試験結果の要旨

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要 旨：

論文提出者は、2013年7月20日午後5時より午後6時まで、志高館SK104で行われた試問会において、審査委員から数多くの質問に対する討論が行われた際、的確な回答をもって本論文の学術的価値を実証し、同時に技術経営、経済学や社会科学に対する十分な学識を持っていることを証明した。

また、日本語の外国語能力認定に際しても、日本におけるヒアリング調査に加え、多数の日本語文献を用いており、十分な実力を有していることが明らかになった。

よって、総合試験の結果は合格であると認める。

博士學位論文要旨

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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.

(2096 Words)