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1. Introduction

To promote public-private linkage in scientific research through policy initiatives, it is essential for policy makers to understand the mechanism for producing, transmitting, and utilizing scientific knowledge between private and public sectors. However, institutional and organizational features of public-private linkage appear to differ from one country to another. Indeed, Japanese innovation system is quite distinct from other advanced countries in many respects[1].

This paper explores salient institutional characteristics which are likely to affect rate and direction of public-private linkage in Japan. In particular, we would like to present policy challenge distilled from the experience in the 1990s in view of (i) public funding scheme, (ii) Japanese pro-patent policy for the public sector, (iii) resource constraint on clinical trials, and (iv) mobility of researchers across private and public sectors. We examine these policy questions focusing on biomedical research, because producing scientific knowledge in biomedical research is closely associated with implementing the knowledge into commercialization, and because life science has been one of the top four prioritized areas (i.e., life science, information and communications, environmental science, and nanotechnologies & materials) in Japanese science and technology policy since the late 1990s[2].

Section 2 explains legislative measures facilitating public-private linkage and public funding scheme in Japan. Traditionally, the Japanese government put top priority to energy-related research such as nuclear fusion. But *The Basic Plan for Science and Technology* which has been introduced every five year period since 1996 has gradually reallocated research expenditures to other technology fields, putting more weight on life science. Since the introduction of the Basic Plan, more than 400 billion yen has been allocated to life science every year[3]. Especially, the establishment of the Council for Science and Technology Policy (CSTP) in 2001 is one of the watershed events which facilitate more flexible allocation of research budget. Unfortunately, however, there are still a lot of defects in public funding scheme. For instance, public fund for research grants is still quite small and very tricky to use.

Section 3 examines the Japanese pro-patent policy. Since the latter half of 1990s, the Japanese government has actively promoted pro-patent policy with intent to advance research collaboration among industry, university and government and to facilitate commercialization of their research outcome. These initiatives reflected considerable interest among Japanese policy makers in emulating the Bayh-Dole Act of 1980 in the U.S. which is widely credited with

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[1] See, for example, Nelson ed. (1993), Odagiri and Goto (1993, 1996), and Henderson et al. (1999).

[2] The present study mentions "public sector" as indicating both government and university. It should be noted, however, that university researchers and government researchers may be very different from each other in propensity to patent, to the extent of their affinity to open science culture, and the resulting values of their patents. We will discuss these points in later sections.

[3] See Council for Science and Technology Policy (2005) for more detail.

stimulating significant growth in university-industry technology transfer and research collaboration. We depict the trend of government and university patenting by assignee types in biomedical fields and discuss possible effects of the Japanese Bayh-Dole policy on biomedical research. We believe that the Japanese Bayh-Dole seems to be just beginning to have some impact on the patenting activity of government research institutes. On the other hand, it does not appear to dictate the patenting behavior of university researchers. Institutional and organizational features of government research institutes and universities are keys to elucidate the salient responses between them.

Section 4 discusses resource constraint on clinical trials. Clinical trial is an important institutional infrastructure for promoting *translational research* which is the combination of basic and applied research producing clinically effective biomedical products or gene therapy/diagnoses. Inventing biomedical products would be one of the ultimate goals of biomedical research. Therefore, if resource constraint on clinical trials is severely binding, it may be all the more difficult to obtain an approval for commercialization of a new biomedical product from competent regulatory agencies. Consequently, a deficient system of clinical trials may weaken incentive to do clinical research not only in the private sector but also in the public sector even if the government actively promotes the pro-patent policy for the public sector.

Section 5 examines mobility of Japanese researchers. Inflexible career trajectory is one of salient characteristics of Japanese researchers. Furthermore, Japanese public sector researchers such as government research institutes and national universities are crusted with rigid office regulations as well as restrictive dual employment rules until quite recently. Accordingly, the low mobility of researchers has possibly caused serious misunderstanding regarding institutional missions, organizational features, and researchers' incentives among industry, government, university. Section 6 closes the present paper with brief concluding remarks.

2. Legislative Initiatives and Public Funding Scheme

Legislative Initiatives Promoting Public-Private Linkage

After the enactment of the *Basic Law on Science and Technology* in 1995, a wave of legislations took place encouraging collaborative research among industry, government and university. A list of the main policy initiatives is provided in Table 1. Several legislative measures actually emulated relevant US policies such as the Bayh-Dole Act and the Small Business Innovation Research (SBIR) program.

[INSERT TABLE 1 AROUND HERE]

Many legislative initiatives were introduced between 1998 and 2000. These legislations were mainly initiated by the Ministry of Economy, Trade and Industry (METI). Among these policy initiatives, *The Law on the Special Measures for Revitalizing Industrial Activities* (The Japanese Bayh-Dole Act) would be quite important, because it has been widely expected to have profound effect on patenting activity and technology transaction, because patenting is regarded as one of the most effective tools for securing privately appropriable knowledge of biotechnologies.

The Japanese Bayh-Dole Act was enacted in 1999 which specified Bayh-Dole provisions in Sections 30 to 33, such as permission of retaining patents to inventions deriving from publicly funded research as well as exclusive licensing of state-owned patents. These provisions reflected considerable interest among Japanese policy makers in emulating the Bayh-Dole Act of 1980 in the U.S.

The Japanese Bayh-Dole Act appears to have had significant effect on the way in which public sector researchers produce privately appropriable research outcome. As will be discussed in the next section, patenting by both government research institutes and universities has exploded since 1999. In addition, the number of patent applications that were filed jointly by both private and public sector researchers also somewhat increased since 1999. However, it is less certain whether the Japanese Bayh-Dole policy really encourage the public sector to file *valuable* patents.

Basic Plan for Science and Technology

In spite of severe economic and fiscal conditions in the 1990s, public funding for science and technology (S&T) has dramatically increased since the latter half of 1990s and reached around 3,580 billion yen as of FY2005. *The Basic Plan for Science and Technology* which has been introduced every five year period since 1996 has gradually reallocated research expenditures to other technology fields, putting more weight on life science.

The First Basic Plan for Science and Technology (1996-2000) initiated several institutional reforms such as tenure system, program to support 10,000 postdoctoral fellows, and industry-government-university collaboration in research. Government R&D expenditure of the First Basic Plan was 17 trillion yen in five years. The Second Basic Plan for Science and Technology (2001-2005) raised the government R&D expenditure to 21 trillion yen in five years, and commanded strategic priority setting in life science, information and communications, environmental science, and nanotechnologies & materials. The Third Basic Plan for Science and Technology (2006-2010) further raised the government R&D expenditure to 25 trillion yen (targeted figure) in five years, and the strategic priority setting of the 2nd Basic Plan is reformulated to extend to other technology fields such as robotics and fuel cell.

Council for Science and Technology Policy

The Council for Science and Technology Policy (CSTP) was established along with the comprehensive reshufflings of administrative organizations in 2001. The main role of this council is to harmonize S&T policies across ministries and agencies at the initiative of the CSTP which is headed by the prime minister. The establishment of the CSTP was one of the watershed events for the proceedings of public research funding, because the initiative in budget allocation of research fund was somewhat shifted to the CSTP across vertically divided competent agencies for the first time in Japan.

The result of a CSTP's review of a research project proposed by a ministry or an agency is reflected, at least partly, in prioritization of budget allocation of the Basic Plan. This review process was officially stipulated as a mission of the CSTP in 2001. For example, every research project is ranked as either S, A, B, or C by the CSTP. It is very likely that a favorable outcome of the CSTP review would ease a budget request negotiation of a jurisdictional authority proposing a particular research project with the Ministry of Finance, even if there are no clearly stated rules relating the review to budget allocation in the letters of the Establishment Act of CSTP.

Prioritization of Public Research Fund

Figure 1 shows the allocation of research budget in FY2005. There are three noteworthy characteristics. First, research grants consist of just around 13% (470 billion yen) of the total budget. Although the budget size of research grants gradually increased in recent years, small sized budge for research grants still contrasts starkly with large outlay in the U.S. where research grants constitute more than 35% of the total S&T budget[4].

Second, there are a lot of government research institutes such as national laboratories and independent administrative agencies (IAAs), and they are generally well funded. Japan Science and Technology Agency (JST), National Institute of Advanced Industrial Science and Technology (AIST), Institute of Physical and Chemical Research (RIKEN), National Agriculture and Bio-oriented Research Organization (NARO), and National Institute of Agrobiological Sciences (NIAS) are closely involved in biomedical research and they account for around 20% of total public R&D subsidies to all IAAs. Roughly, the S&T budget for government research institutes amounts equally to the budget for universities. It should be noted that the number of government researchers is just around 34,000 whereas there are about 291,000 researchers in universities in FY2004[5].

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[4] See CSTP (2002) for detail.

[5] See Section 5 for detail.

Third, government research funds are sprinkled through many vertically divided funding agencies. There is no presiding agency regarding life science in Japan like National Institute of Health (NIH) in the U.S. In addition, there is no integrated serial numbers of researchers across agencies and there is no common guiding principle of peer review across agencies, which is possibly conducive to the small number of star scientists obtaining much larger volume of research funds from multiple funding agencies.

These characteristics are likely to reinforce the tendency of the so-called *Matthew effect* in science (Merton, 1968; Dasgupta and David, 1994). That is, an eminent scientist will obtain more research funds than a comparatively unknown researcher even if their works are similar to each other[6]. Furthermore, research grants have been concentrated on a few prominent top national universities. For example, the share of research grants by top 10 national universities is more or less 50% in Japan, and Tokyo University obtains around 15% of total Grants-in-Aid by the Ministry of Education, Culture, Sports, Science and Technology (MEXT)[7].

[INSERT FIGURE 1 AROUND HERE]

Table 2 shows public expenditures by categories during the Second Basic Plan. The four prioritized research areas (life science, information and communications, environmental science, and nanotechnologies & materials) accounted for almost 40% of the total public R&D expenditures in 2001 and the share was increased during the Second Basic Plan for the years 2001-2005. This fact demonstrates the initiative by CSTP working effectively. It is quite unusual in the Japanese budget allocation system that research budget is flexibly reallocated year by year, because each segment of the budget is closely related to vested interests of vertically divided ministries and agencies.

[INSERT TABLE 2 AROUND HERE]

Research Grants

Almost all Japanese universities and government research institutes are funded predominantly by the government and are tightly controlled by competent ministries and agencies[8]. The most

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[6] *"For unto every one that hath shall be given, and he shall have abundance: but from him that hath not shall be taken away even that which he hath."* (Matthew XXV:29, KJV).

[7] See CSTP (2002) for more detail.

[8] Odagiri and Goto (1993, 1996), Odagiri (1999), Kneller (2003), and Walsh and Cohen (2004) provide beneficial information about organizational and institutional differences between Japan and the U.S. regarding public research and its collaboration with industry. They suggest that public research has a substantial impact on industrial R&D in both countries, although the institutional environments for university-industry linkages in the two countries are quite distinct.

important sources of research grants for Japanese universities are Grants-in-Aid (188 billion yen in FY2005) and Center-of-Excellence 21st Century Grants (38 billion yen) by MEXT, and Adjustment Outlays for Promoting Science and Technology (40 billion yen) by JST.

Table 3 shows main differences in execution proceedings between Japan and U.S. regarding representative research grants (grants-in-aid by MEXT in Japan, and grants by NIH and NSF in the US). As is described in Table 3, Use of research grants in Japan is very restrictive. For example, personnel expense for core project researchers is prohibited except part-time employment of graduate students and postdoctoral fellows; carried-over expense across fiscal year is not allowed by rigorous one fiscal-year budget constraint; and the opportunity of subscriptions is once a year in all types of research grants in Japan.

[INSERT TABLE 3 AROUND HERE]

Inflexible use of research grants appear to have induced university researchers to prefer informal collaboration with industry researchers rather than to muddling through red-tape routines in collecting donations from the private sector, hiring temporary researchers, contracting commissioned research, and negotiating the ownership of research outcomes, with quite a few administrative officers under one-fiscal year budget constraint[9].

3. Government and University Patenting in Biomedical Fields

Japanese Bayh-Dole Act

Among the policy initiatives in Table 1, the Japanese Bayh-Dole Act is particularly important because it has been widely expected to have profound effect on patenting activity and technology transaction of the public sector. As is well known, the Japanese economy in the 1990s is called as “a lost decade” with gnawing stagnation[10]. The economic condition behind the pro-patent movement in the 1990s is in marked contrast to the US economic condition in the 1970s which motivated the introduction of the Bayh-Dole Act in 1980.

The Japanese Bayh-Dole Act and other auxiliary measures appear to have had significant effect on the way public sector researchers produce privately appropriable research outcome in biomedical fields. Patenting by both government research institutes and universities has exploded since the introduction of the Japanese Bayh-Dole Act. In addition, the number of patent applications that were filed jointly by both private and public sector researchers also increased since 1998.

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[9] See Odagiri (1999) and Kneller (2003) for similar observations.

[10] See, for example, Hayashi and Prescott (2002).

Figure 2 depicts the share of patents by various assignee types[11]. In biomedical research, there is an increased trend of patenting by the public sector. The share of patents that were filed by the public sector almost trebled in the late 1990s and reached almost 30% of total patents in 2002[12].

[INSERT FIGURE 2 AROUND HERE]

Figure 3 shows the trend of patenting by assignee types. It is worth noting that patenting by the public sector as a single assignee has particularly increased since the introduction of the Japanese Bayh-Dole Act. The number of jointly filed patents by both private and public sectors is also increasing, but somewhat lagging behind. We think that institutional features of government research institutes and universities are keys to elucidate the salient responses between them.

[INSERT FIGURE 3 AROUND HERE]

Government Patenting

Government patenting is highly concentrated with the following top 5 government research institutes: JST, AIST, RIKEN, NARO, and NIAS[13]. As shown in Table 4, they account for almost 70% of the total application by the government, and the top 3 government institutions (i.e., JST, AIST and RIKEN) occupy the majority of government patents. This may partly reflect the fact that government subsidies are somewhat concentrated on these research institutes[14].

[INSERT TABLE 4 AROUND HERE]

We believe that the government research institutes have been strongly encouraged to file patents by jurisdictional authorities since the introduction of the First Basic Plan for Science

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[11] Concerning data construction procedure such as retrieval of patent data and assignee name matching, see Okada et al. (2006) in detail.

[12] Here we define the share of the public sector patents consisting of a single assignee (i.e., government and university) and multiple co-assignees (i.e., government and corporation, university and corporation, and government and university). The share of the public sector patent was less than 10% in the early 1990s, but it has been rapidly increased since the late 1990s and reached 29.1% in 2002.

[13] The top 5 government institutes are defined by the order of the total patent applications since 1991 through 2002 in biomedical research. Jurisdictional authorities are as follows: MEXT for JST and RIKEN; METI for AIST; and Ministry of Agriculture, Forestry and Fisheries (MAFF) for NARO and NIAS. The jurisdictional relationships were not changed before and after reorganizations which had occurred several times in the 1990s.

[14] These five research institutes account for around 20% of total public R&D subsidies to independent administrative agencies (IAAs). Concerning the distribution of government research expenditures among public research institutes, see NISTEP (2005) for detail.

and Technology, because the number of patents (as well as patent licenses) is regarded as one of important performance indexes in annual reviews by CSTP. In addition, the government research institutes are tightly supervised by vertically divided bureaucracy, thereby they are likely to be controlled via administrative guidance in a more expeditious way compared with universities.

University Patenting

For most university researchers, patenting may be far from ordinary academic lives. Most major research universities are national universities and although they are closely supervised by MEXT, publication of academic papers seems to be much more important than patenting, as is the case in the U.S. top research universities[15]. Increased trend of university patenting since 1998 may be partly explained by the recent facilitating policy measures which somewhat alleviated red-tape routine in government research funding and negotiations with the private sector concerning the ownership of research outcome and licensing conditions. However, as we discuss below, transferring scientific knowledge from university to industry through formal contracts such as patent licensing appears to be at a rudimentary stage.

Commercialization of Scientific Knowledge and Patent Value

The Law on the Promotion of Technology Licensing by Universities etc. (the TLO Act) which was enacted in 1998 states that the government should support technology licensing organizations (TLOs) of universities and government research institutes. In addition, universities and government research institutes should obtain partial remission of patent fees, and the licensees from the *approved* TLOs by the government may be given government investment under certain conditions. The TLO Act possibly encouraged the public sector to establish TLO. Patenting by the public sector would also be significantly stimulated with the assist of the Japanese Bayh-Dole Act. However, the licensing activity by TLOs has not been very impressive, as yet, in Japan. Table 5 compares patenting and licensing activities of technology licensing organizations (TLOs) between Japan and U.S. Although the number of patent which are owned by the Japanese TLOs is now quite large, royalty revenues by them are still hover at a low level.

[INSERT TABLE 5 AROUND HERE]

As Argyres and Liebeskind (1998) indicate, the commercialization of government/university research would be hampered because of their historic commitment to

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[15] See, for example, Mowery et al. (2001) and Agrawal and Henderson (2002).

create and sustain "intellectual commons" for the public at large. Informal free flow of knowledge between public and private sectors may be an important source of social benefit. Patenting may thereby inhibit diffusion of scientific knowledge, which has been christened "the tragedy of anticommons" by Heller and Eisenberg (1998).

In a related vein, Mowery and Sampat (2005) convincingly argue that the efforts at emulation of the Bayh-Dole policy are likely to have modest success at best without greater attention to the underlying structural differences among the higher education systems. Mowery and Sampat (2005, p.123) also suggest that the emulated Bayh-Dole policies by OECD countries, including Japan, "ignore one of the central justifications for Bayh-Dole, i.e., that government ownership of publicly funded inventions impedes their commercialization."

Even though patent statistics would be a beneficial source of information about the role of the public sector and its research collaboration with the private sector in commercializing research outcome, it is less certain whether the value of patents filed by the public sector is concomitantly increased by the pro-patent policy. Patent value analysis by the public sector is therefore quite important because they are closely associated with the intensity of licensing activity.

There are several prior studies concerning the Bayh-Dole Act in the US. See, for example, Henderson et al. (1998), Mowery et al. (2001), Mowery and Ziedonis (2002), Thursby and Thursby (2002), Mowery and Sampat (2005), Hall (2005), among others. These studies provoke, to a greater or lesser degree, a cautious view to pro-patent policy, toward the Bayh-Dole-like measure in particular.

Concerning the Japanese Bayh-Dole, we suggest, in a recent study, that the value of patents by government research institutes began to increase since the introduction of the pro-patent policy in the late 1990s. On the other hand, there is no significant change in the value of university patents before and after the Japanese Bayh-Dole Act, thus the Japanese pro-patent policy does not appear to dictate the patenting behavior of university researchers regarding their "important" inventions (Okada et al., 2006).

4. Clinical Research and Medical Evaluation Scheme

Inactive Translational Research in Japan

Clinical research is likely to commence after priority of patents are secured. Inventing biomedical products would be one of the ultimate goals of long-term biomedical research process. Basic biomedical research and clinical research have distinct features in terms of required knowledge, cost structure and stage-specific skill. Therefore pro-patent policy measures would not necessarily facilitate clinical research.

Translational research is the combination of basic and applied research producing clinically effective biomedical products or gene therapy/diagnoses. Post-genome technologies such as gene function, protein conformation, and protein function are essential to perform translational research. However, the number of patents of this sort is not, as yet, impressive in Japan. Translational research may be one of the weakest areas in Japanese biomedical research.

On the other hand, basic research such as genetic engineering and gene analysis are the most active fields in patenting in Japan, although these technologies are rather upstream technologies in the long-term process of biomedical research and they are, if anything, mature research fields[16]. The rapid growth of patenting in genetic engineering and gene analysis may be partly due to the enlargement of patentable domain in the early 1990s. Roughly speaking, the patentable domain in Japan is ranked somewhere in between the broader scope of the US and the narrower scope in EU[17].

Hollowing Out of Domestic Clinical Trials

Figure 4 plots the number of notifications of clinical trials in Japan. The reasons for the rapid decrease in clinical trials in the early 1990s would be caused by: (i) the adoption of a stricter standard for screening proceedings in 1998 which is based on ICH (The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use); (ii) many last-minute applications in the early 1990s before the reforms of Drug Legislation Act in 1997 which was expected to prolong examination periods at that time; and (iii) several drug lawsuits such as *the Sorivudine case* and *the HIV-contaminated blood products case*. As of 1997, ready and waiting notifications reached around 300.

[INSERT FIGURE 4 AROUND HERE]

According to Office of Pharmaceutical Industry Research (2000), Japanese pharmaceutical companies increasingly start clinical trials overseas, particularly in the U.S. In 1993, the ratio of clinical trials overseas to the total clinical trials for new chemical entities developed by Japanese pharmaceutical companies is 18.3%, but the ratio increased to 43.2% in 2000.

Binding resource constraints of clinical trials would retard approvals for commercialization of biomedical products. Table 6 shows main differences among major advanced countries regarding institutional characteristics of clinical trials in 1997. There are two types of organizational structure of clinical trials. Main examiners are inside experts in UK and

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[16] See Okada et al. (2006).

[17] See Japan Patent Office (2003) for more detail.

US. On the other hand, in EU and France, a large number of outside experts are nominated and some of them are selected on case by case basis. In Japan, there were drastic reorganizations of the clinical trial system in 1997 and 2004. Organizational structure of the clinical trials are now shifting from the outside-oriented to inside-oriented expert panels, but the number of inside experts remains to be quite small in Japan.

[INSERT TABLE 6 AROUND HERE]

Ministry of Health, Labor and Welfare herself suggests that the main reason for the *hollowing out* would be a poor clinical trials infrastructure[18]. Implementation structure and incentives for both clinical researchers and clinical study participants are not good enough in terms of funding as well as contracting scheme. The number of clinical research coordinators is also quite few in many national hospitals and national universities which are the main implementing agencies in Japan. The hollowing out of clinical trials may further cause slower access to new drug treatments and deterioration of the capability of clinical research by industry, medical doctors, and universities.

5. Low Mobility of Researchers

Inflexible career-path of researchers is one of salient characteristics of the Japanese researchers' job market. Figure 5 depicts researchers' recruitment and retirement processes as well as movements among industry, government, and university. It is quite infrequent for Japanese researchers to move across industry, government and university throughout their career trajectories. For example, only 1.1% of total researchers (8,775/790,932) switched their career-path across the walls of industry, government and university in 2004. In addition, even if job-switching occurs, the end point of the career path is likely to be a university. The moves inside of a wall are also quite infrequent. The shares of job switching researchers are 3.1% for corporations (14475/465,891), 2.3% for universities (6606/291,147), and 6.6% for public research institutions (2,242/33,894). There would be a lot of reasons for the low mobility of researchers in Japan, such as inflexible employment contract, immobile pension scheme, and seniority-based wage system, particularly in the public sector.

[INSERT FIGURE 5 AROUND HERE]

It is worth noting that the Japanese Bayh-Dole Act in 1999 further stipulates somewhat flexible dual employment rule across private and public affiliations for the first time in Japan.

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[18] See Ministry of Health, Labor and Welfare (2002) for more detail.

Furthermore, *the Law on the Enhancement of Industrial Technologies* which was enacted in 2000 made much further clarifications on the dual employment rule. We think that the dual employment provisions are no less important than the Bayh-Dole provisions in view of the inflexible job market of researchers in Japan.

The Law on the Enhancement of Industrial Technologies stipulates that the government should take into account the significance of dual employment of the public sector researchers as a board member of for-profit entities in terms of transferring academic research outcome, and that the government should introduce necessary policy measures to facilitate commercialization of the research outcome of the public sector[19]. However, as is apparent in Figure 5, the effect of these laws and other related ministerial ordinances has had only a limited effect, as yet, on the extent of researchers' mobility, not to mention dual employments.

Organizational Reforms for Public Sector Research

The low mobility of researchers has possibly caused serious misunderstanding regarding institutional missions, organizational features, and researchers' incentives among government, industry, and university. Furthermore, Japanese public sector researchers are crusted with rigid office regulations and restrictive dual employment rules. Contrary to the U.S., Japanese university researchers have to abide by strict office regulations which are virtually similar to those for civil servants.

In fact, there have been several organizational reforms for the public sector since 2001. In April 2001, almost all public research institutes were reorganized into "independent administrative agencies" (IAAs) which seem to be independent of the government as literally interpreted. But they have been financially as well as managerially supervised tightly by vertically divided competent ministries and agencies.

As for Japanese national universities, they were reorganized to semi-private entities (so-called "national university foundations") in April 2004. National university foundation is an intermediate legal entity in between government agency and public foundation. In exchange for this reform, government subsidy to Japanese national universities has been undercut by 1% every year since 2004. This numerical target is called the streamlining coefficient (*kourituka-keisu*).

These organizational reforms are called agencification (*houjin-ka*) and widely expected to improve organizational efficiency of universities (as well as government research institutes, perhaps, in slightly different ways). However, mainly due to somewhat less expeditious responses by universities, the real effect of this reform still remains to be seen.

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[19] Kneller (2003) provides beneficial information about organizational and institutional differences between Japanese and the U.S. universities in more detail.

6. Concluding Remarks

The role of the public sector is possibly important in biomedical research. Biomedical research is characterized by the high importance of basic research done at universities and public research institutions. However, there are many steps before basic research leads to commercialization. Producing and transmitting scientific knowledge can take a wide variety of forms depending on research areas, organizations, participants, and other factors. Accordingly, there is no single answer with respect to methods of public support for biomedical research. Consequently, public support for research, pro-patent policy measures in particular, must be designed with sufficient attention to the characteristics of institutional and organizational features of the public sector on a case-by-case basis.

We think that flexible funding scheme and higher mobility of researchers are keys to improve public-private linkage in Japan. The low mobility of researchers has possibly caused serious misunderstanding regarding institutional as well as organizational features and researchers' incentives. This may make it all the more difficult for Japanese researchers to do public-private collaborative research in an expeditious way.

References

Agrawal, A. and R. Henderson (2002) "Putting Patents in Context: Exploring Knowledge Transfer from MIT," *Management Science* 48(1), 44-60.

Argyres, N. S. and J. P. Liebeskind (1998) "Privatizing the Intellectual Commons: Universities and the Commercialization of Biotechnology," *Journal of Economic Behavior & Organization* 35, 427-454.

Council for Science and Technology Policy (2002), *Reports on the Reform for Competitive Research Grants* (in Japanese).

Council for Science and Technology Policy (2005), *Reports of the Expert Panel on the Basic Policy*. (http://www8.cao.go.jp/cstp/english/index.html)

Dasgupta, P. and P. David (1994) "Toward a New Economics of Science," *Research Policy* 23, 487-521.

Hall, B. H. (2005) "Exploring the Patent Explosion," *Journal of Technology Transfer* 30, 35-48.

Hayashi, F. and E. C. Prescott (2002) “The 1990s in Japan: A Lost Decade,” *Review of Economic Dynamics* 5, 206-235.

Heller, M. and R. Eisenberg (1998) “Can Patents Deter Innovation? The Anticommons in Biomedical Research,” *Science* 280, 698.

Henderson, R., M. Trajtenberg and A. Jaffe (1998) “Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965-1988,” *Review of Economics and Statistics* 80(1), 119-127.

Henderson, R., L. Orsenigo and G. P. Pisano (1999) “The Pharmaceutical Industry and the Revolution in Molecular Biology: Interactions among Scientific, Institutional, and Organizational Change,” in D. C. Mowery and R. R. Nelson eds., *Sources of Industrial Leadership,* Cambridge University Press, 267-311.

Japan Patent Office (2003), *Reports on Technology Trend and Patent Application: Life Science,* (in Japanese).

Kneller, R. (2003) “University-Industry Cooperation and Technology Transfer in Japan Compared with the US: Another Reason for Japan’s Economic Malaise?” University of Pennsylvania Journal of International Economic Law 24, 329-450.

Merton, R. K. (1968) “The Matthew Effect in Science” *Science* 159, 3810, 56-63.

Ministry of Health, Labor and Welfare (2002) *Visions of Pharmaceutical Industry in Japan* (http://www.mhlw.go.jp/houdou/2002/04/h0409-1.html) (in Japanese).

Mowery, D. C., R. R. Nelson, B. N. Sampat, and A. A. Ziedonis (2001) “The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980,” *Research Policy* 30(1), 99-119.

Mowery, D. C. and B. N. Sampat (2005) “The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?” *Journal of Technology Transfer* 30 1/2, 115-127.

Mowery, D. C. and A. A. Ziedonis (2002) “Academic Patent Quality and Quantity Before and

After the Bayh-Dole Act in the United States," *Research Policy* 31(3), 399-418.

Nelson, R. R. ed. (1993) *National Systems of Innovation*, Oxford: Oxford University Press.

NISTEP (2005) *Survey on the Performance of the 1st and the 2nd Science and Technology Basic Plan*, National Institute of Science and Technology Policy (NISTEP) Report No.84 (in Japanese).

Odagiri, H. (1999) "University-Industry Collaboration in Japan: Facts and Interpretations," in L. M. Branscomb, F. Kodama and R. Florida, eds., *Industrializing Knowledge*, Cambridge MA: MIT Press, 252-265.

Odagiri, H., and A. Goto (1993) "The Japanese System of Innovation: Past, Present and Future," in R. R. Nelson ed., *National Systems of Innovation*, Oxford: Oxford University Press, 76-114

Odagiri, H. and A. Goto (1996) *Technology and Industrial Development in Japan: Building Capabilities by Learning, Innovation and Public Policy*, Oxford: Oxford University Press.

Okada, Y., K. Nakamura and A. Tohei (2006) "Is there a Significant Contribution of Public Sector in Biomedical Research in Japan? A Detailed Analysis of Government and University Patenting, 1991-2002," COE-RES Discussion Paper Series, no.175, Hitotsubashi University. (http://www.econ.hit-u.ac.jp/~coe-res/index.htm)

Office of Pharmaceutical Industry Research (2000) *Seiyaku Sangyou Ron* (*Analyses on Pharmaceutical Industry*), Japan Pharmaceutical Manufacturers Association (in Japanese).

Thursby, J. G., and M. C. Thursby (2002) "Who is Selling the Ivory Tower? Sources of Growth in University Licensing," *Management Science* 48, 90-104.

Walsh, J. P., and W. M. Cohen (2004) "Does the Golden Goose Travel? A Comparative Analysis of the Influence of Public Research on Industrial R&D in the U.S. and Japan," mimeo.

Table 1 Legislative Initiatives in Japan

Year	Initiatives	Major provisions
1995	The Basic Law on Science and Technology	The Basic Law on Science and Technology states that the government should declare the direction of promotional initiatives for science and technology (S&T), and achieve a national consensus on the promotion of S&T; that the government should formulate a *Five-year Basic Plan* for S&T in order to comprehensively and consistently implement policies.
1996-2000	The First Basic Plan for Science and Technology	Promotion of institutional reforms, such as tenure system, program to support 10,000 post-doctorals, and industry-government-university collaboration in research. Increase in government R&D expenditure (17 trillion yen in five years).
1998	The Law on the Promotion of Technology Licensing by Universities, etc.	The so-called TLO Act. Subsidization to the approved TLOs of universities, national research institutes, etc. Partial remission of patent fee. Government investment to licensees.
1998	The Law on the Promotion of Research Exchange	Remission to the rent of state-owned real estates and facilities for the use of industry-university-government collaborative research.
1999	The Law on the Special Measures for Revitalizing Industrial Activities	The so-called "Japanese Bayh-Dole Act," including Bayh-Dole provisions, such as permission of retaining patents to inventions deriving from publicly funded research as well as exclusive licensing of state-owned patents. Permission of dual employment of university/government researchers.
1999	The Law on the Promotion of New Business Incubation	The so-called "Japanese *SBIR* program". Debt guarantee for new business incubation.
2000	The Law on the Enhancement of Industrial Technologies	Clarifying dual employment rules for the researchers of national universities/government research institutes. Partial remission of application/ grant fee of patents filed by university/government researchers.
2001	Reorganization of the national research institutes into independent administrative agencies (IIA)	Almost all public research institutes were reorganized into “independent administrative agencies” (IAAs) which seem to be independent of the government as literally interpreted. But they have been financially as well as managerially supervised tightly by vertically divided bureaucracy.
2001	The Council for Science and Technology Policy (CSTP)	This council was established along with the comprehensive reshuffling of administrative organizations in 2001. The main role of this council is to harmonize S&T policies across ministries and agencies at the initiative of the CSTP (headed by the prime minister).
2001-2005	The Second Basic Plan for Science and Technology	Raising the government R&D expenditure to 24 trillion yen in five years. Strategic priority setting in S&T (technologies on life science, information and communications, environmental science, and nano-technologies & materials).
2002	Biotechnology Strategic Scheme	The Biotechnology Strategy Council is being convened since 2002 in order to establish a BT strategy for Japan and to advance the necessary policies. The current scheme (Biotechnology Strategic Scheme) was adopted in 2002.
2002	The Basic Law on Intellectual Property	The Basic Law on Intellectual Property states that the government should promote creation, protection, and utilization of intellectual properties. Following this law, the Strategic Council on Intellectual Property was established in 2002.
2004	The Law on National University Foundations	Japanese national universities were reorganized to semi-private entities, so-called “national university foundations,” in April 2004. National university foundation is an intermediate legal entity in between government agency and public foundation.
2006-2010	The Third Basic Plan for Science and Technology	Raising the government R&D expenditure to 25 trillion yen in five years. The strategic priority setting of the 2nd Basic Plan is reformulated to extend to other technology fields such as robotics and fuel cell (FC).

Table 2 Public Expenditures on Science and Technology in Japan

(billion yen, fiscal year)

	2001	2002	2003	2004
Life Science	390.7	393.4	427.0	436.2
Information Technologies	166.3	175.8	169.6	175.8
Environment	84.7	100.6	109.9	117.5
Nano-technologies /Materials	80.4	85.6	91.2	94.0
Energy	685.6	705.0	671.4	682.6
(Nuclear Energy)	(370.9)	(338.3)	(340.6)	(302.9)
Manufacturing Technologies	23.2	16.4	19.8	20.3
Infrastructure	266.0	255.4	256.1	263.6
Frontiers (Space / Marine)	306.2	295.3	302.9	281.4
Subtotal (Top 4 Priorities)	722.1	755.4	797.7	823.5
	(36.0%)	(37.3%)	(39.0%)	(39.4%)
Total	2003.1	2027.3	2047.9	2091.4

Data Source: The Council for Science and Technology Policy (CSTP)

Note: Figures in the table do not include expenditures for either cross-disciplinary research or university research (around 1.5 trillion yen every year).

Table 3 Execution Proceedings of Representative Research Grants

		Japan	US	
Grants		Japan Society for the Promotion of Science (JSPS)	National Institutes of Health (NIH)	National Science Foundation (NSF)
Frequency of subscription		Once a year (adoption in April; fund allocation in June)	Three times a year (Feb, June, and Oct)	Year-round subscription
Account settlement		31 March in each year	End year of a project	
Carrying-over of research fund		Prohibited (rigid one fiscal-year budget constraint)	Completely free within a timeframe of research project	
Virement		Upperbound of 3 million yen or 30% of total grants in each fiscal year	No restriction	
Coverage of direct cost of grants	Personnel cost	Part-time employment expense for post-docs and graduate students (wage expense for core researchers is prohibited)	Wages for professors, core researchers, post-docs, technicians, graduate students, secretary, fringe benefits etc.	
	Travel expense	Core researchers only	Core researchers and graduate students	
	Others	facilities and equipment, expendables, printing, services, rewards, expenses for invited researchers	facilities and equipment, expendables, printing, services, rewards, expenses for invited researchers	

Source: *Reports on the Reform of Research Grants* (CSTP, 2002)

Table 4 Top 5 Government Research Institutes in Biomedical Fields

#	Organization	Patent application	%	Top 3 (%)	Top 5 (%)
1	Japan Science and Technology Agency (JST)	676	25.1	56.7	70.4
2	National Institute of Advanced Industrial Science and Technology (AIST)	528	19.6		
3	The Institute of Physical and Chemical Research (RIKEN)	322	12.0		
4	National Agriculture and Bio-oriented Research Organization (NARO)	191	7.1		
5	The National Institute of Agrobiological Sciences (NIAS)	177	6.6		
	Total	2692			

Note: These data are based on biotechnology patents whose priority years are from 1991 to 2001 and the priority country is Japan. The top 5 research institutes are defined due to the order of the total number of patent application since 1991 through 2001 in biotechnologies. See Okada et al. (2006) for more detail.

Table 5 Technology Licensing Organization in Japan and the U.S.

	Japan (FY2005)	US (FY2003)
TLOs	41	165
Patents	1226	7203
Licenses	626	3855
Revenue from licensing	2.9 billion yen	110 billion yen [a)]

a) Calculated by the exchange rate in 2003.
Data Source: CSTP (2005)

Table 6 Institutional Characteristics on Medicine Evaluation Agencies in 1997

	US	EU	UK	France	Japan
Organization	Food and Drug Administration (FDA)	European Medicine Evaluation Agency (EMEA)	Medicine Control Agency (MCA)	Pharmaceutical Affairs Bureau (FMA)	Organization for Pharmaceutical Safety and Research (OPSR)
Staff [a)]	1806 (examiners only)	157 (total)	414 (total)	500 (total)	164 (53 in Ministry of health and 111 in OPSR)
Outside expert	21 committees with 210 experts	60 rapporteurs (Committee for Proprietary Medicinal Products: CPMP/Committee for Veterinary Medicinal Products: CVMP) and 2000 outside experts	22 experts in Committee on Safety of Medicines	1000 outside experts	650 outside experts in Central Pharmaceutical Affairs Council
Main examiner	inside examiners	rapporteurs and outside examiners	inside examiners	outside examiners	inside and outside examiners
Average review period [b)]	Document review with 2 months, substantive review with 6 month (8 months in total)	300 days	120 days (90 days extension is possible)	120 days (90 days extension is possible)	18 months
	17.8 month (1996)	about 1 year	a little less than 1 year (1995-96)	200-220 days (1996)	2.5-3 years

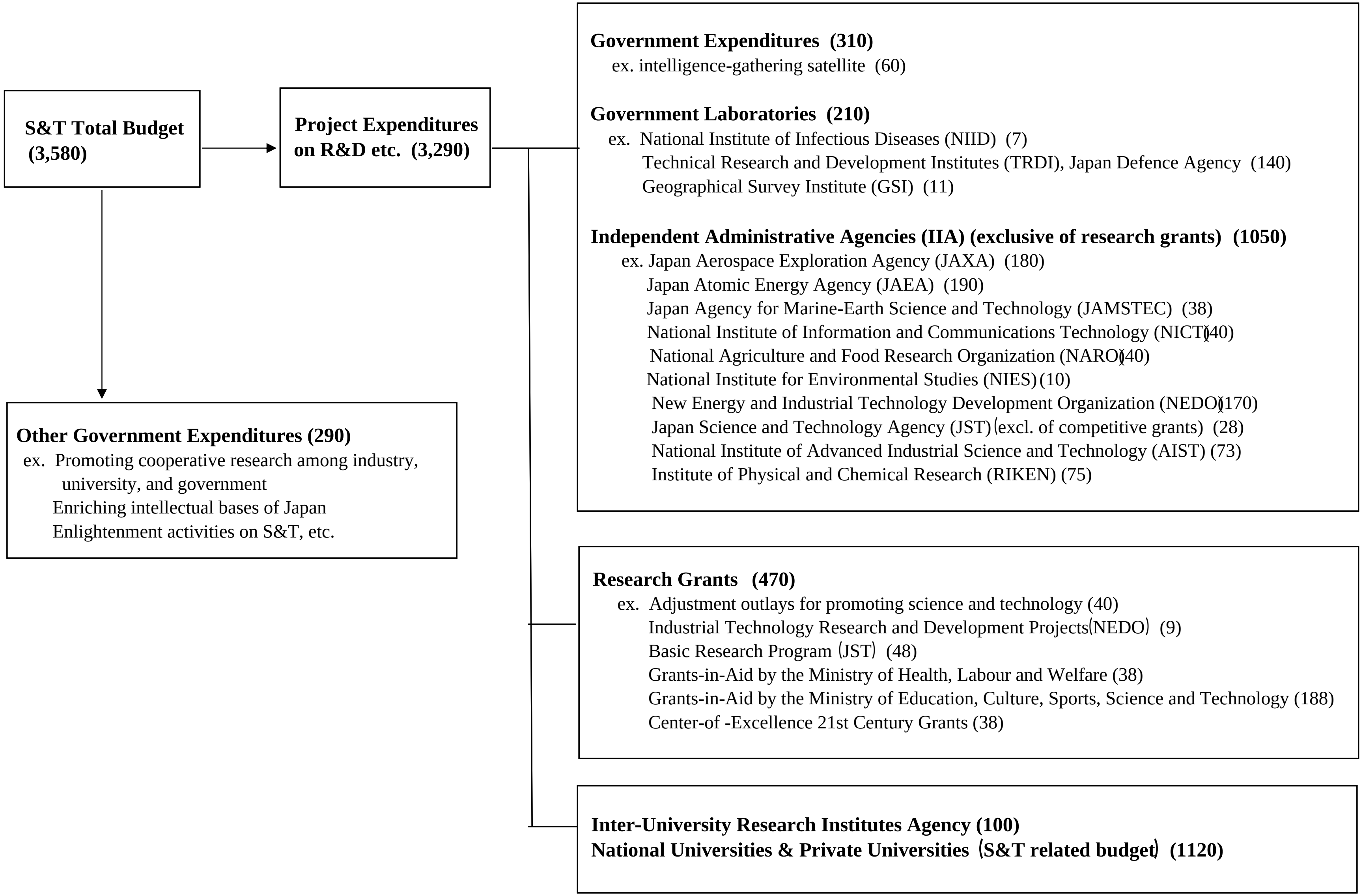
a) The number of staff in the table are for FY1997 except for France (FY1996).

b) Upper, standard administrative proceedings: lower; actual proceedings.

Data source: FDA, PDUFA II Five-Year Plan; MCA, Annual Report and Accounts 1997/1998; EMEA, Third General Report 1997; France, Parexel, New Drug Approval in France; Japan Pharmaceutical Manufacturers Association.

Source: *Reports on the Organizations of Medical Evaluation Agencies* (JPMA, 1999): *Survey on Actual Conditions Regarding Access to Japan Phamaceuticals* (JETRO, 1998)

Figure 1 National Expenditures on Science and Technology (S&T) in Japan, FY2005 (billion yen)



S&T Total Budget (3,580)

Project Expenditures on R&D etc. (3,290)

Other Government Expenditures (290)
ex. Promoting cooperative research among industry, university, and government
Enriching intellectual bases of Japan
Enlightenment activities on S&T, etc.

Government Expenditures (310)
ex. intelligence-gathering satellite (60)

Government Laboratories (210)
ex. National Institute of Infectious Diseases (NIID) (7)
Technical Research and Development Institutes (TRDI), Japan Defence Agency (140)
Geographical Survey Institute (GSI) (11)

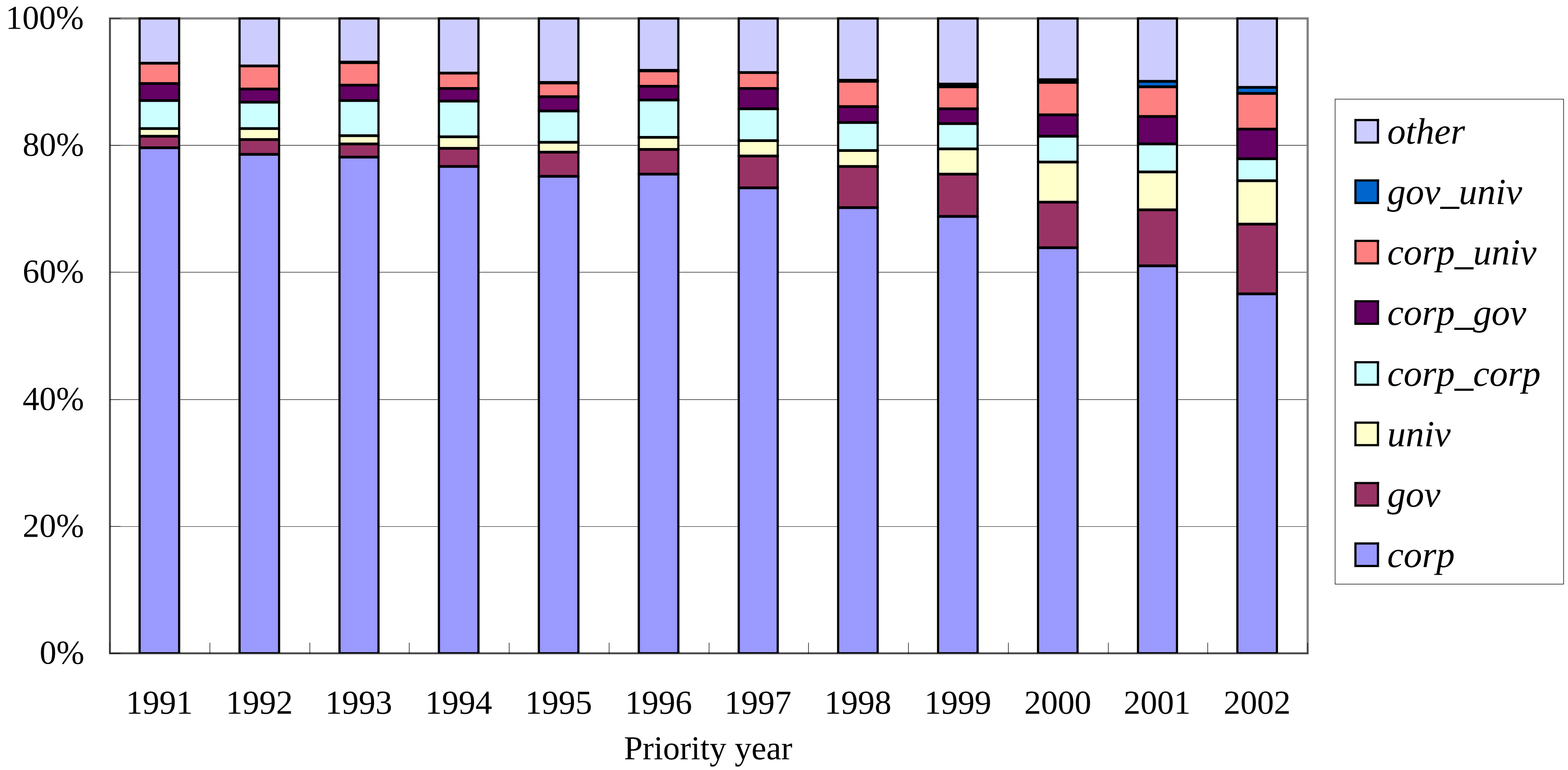
Independent Administrative Agencies (IIA) (exclusive of research grants) (1050)
ex. Japan Aerospace Exploration Agency (JAXA) (180)
Japan Atomic Energy Agency (JAEA) (190)
Japan Agency for Marine-Earth Science and Technology (JAMSTEC) (38)
National Institute of Information and Communications Technology (NICT)(40)
National Agriculture and Food Research Organization (NARO)(40)
National Institute for Environmental Studies (NIES) (10)
New Energy and Industrial Technology Development Organization (NEDO)(170)
Japan Science and Technology Agency (JST) (excl. of competitive grants) (28)
National Institute of Advanced Industrial Science and Technology (AIST) (73)
Institute of Physical and Chemical Research (RIKEN) (75)

Research Grants (470)
ex. Adjustment outlays for promoting science and technology (40)
Industrial Technology Research and Development Projects (NEDO) (9)
Basic Research Program (JST) (48)
Grants-in-Aid by the Ministry of Health, Labour and Welfare (38)
Grants-in-Aid by the Ministry of Education, Culture, Sports, Science and Technology (188)
Center-of -Excellence 21st Century Grants (38)

Inter-University Research Institutes Agency (100)
National Universities & Private Universities (S&T related budget) (1120)

Source: *Reports on the Expert Panel on the Basic Policy*, Council for Science and Technology Policy (CSTP), Cabinet Office, 2005/200

Figure 2 Biotechnology patent by assignee type (%)



Notes: *corp* : corporations. *gov* : government research institutes. *univ* : university. *corp_gov* denotes patents filed by both corporations and government research institutes. *corp_univ* denotes patents filed by corporations and universities. *corp_corp* denotes the jointly filed patents by corporations. *gov_univ* denotes patents filed by government research institutes and universities.

Figure 3 Biomedical patents filed by the public sector (base year: 1991 = 100)

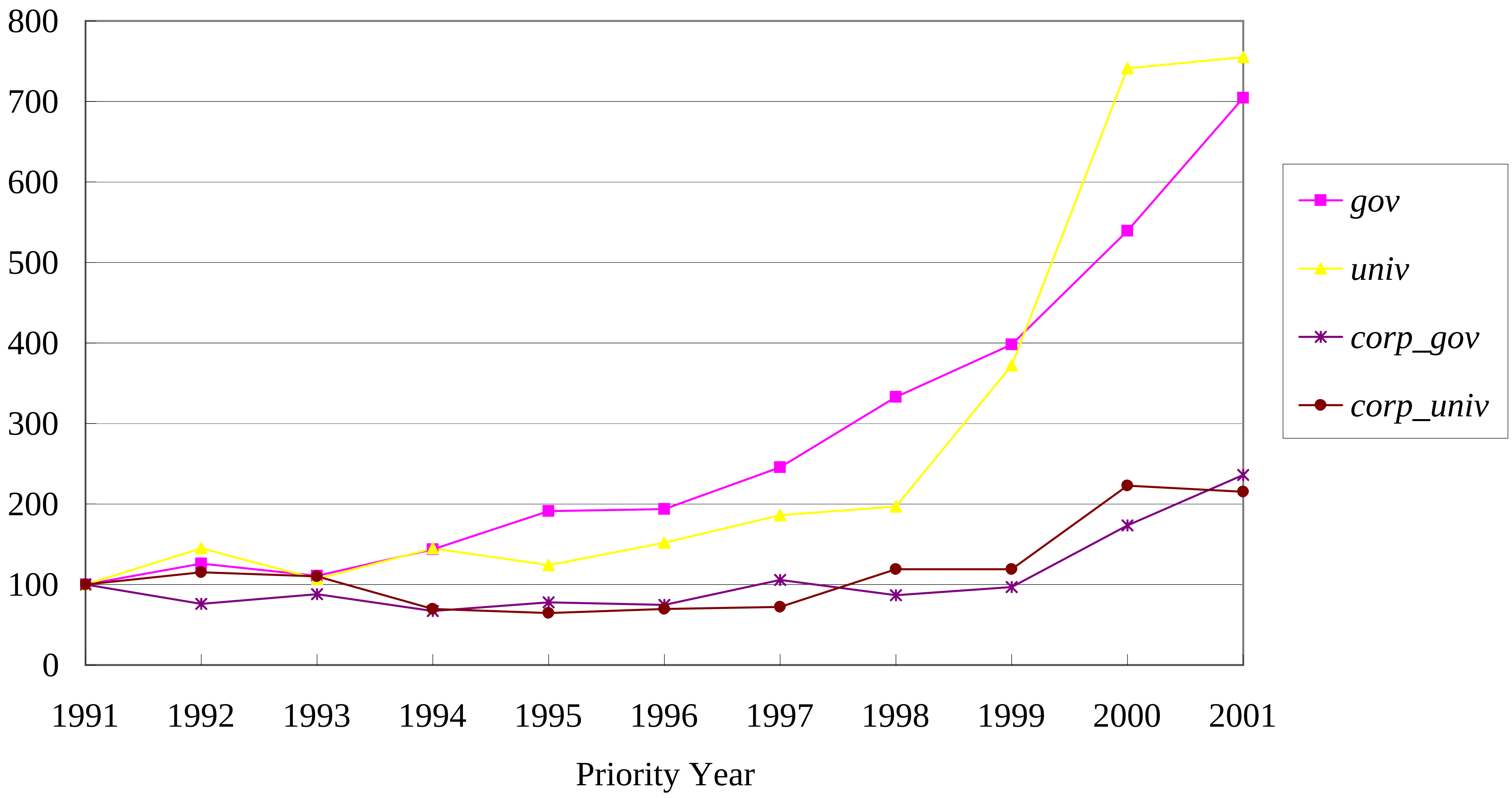
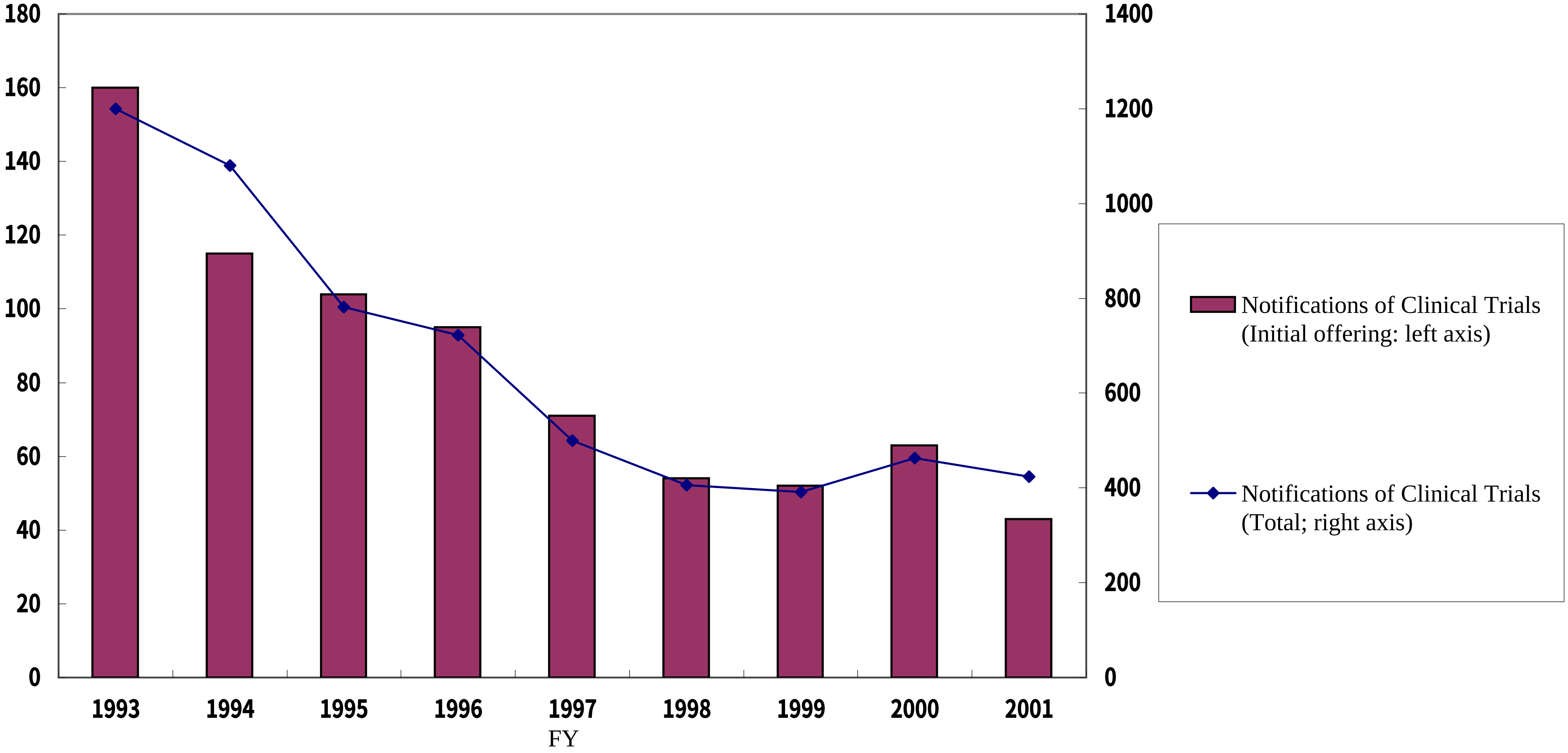
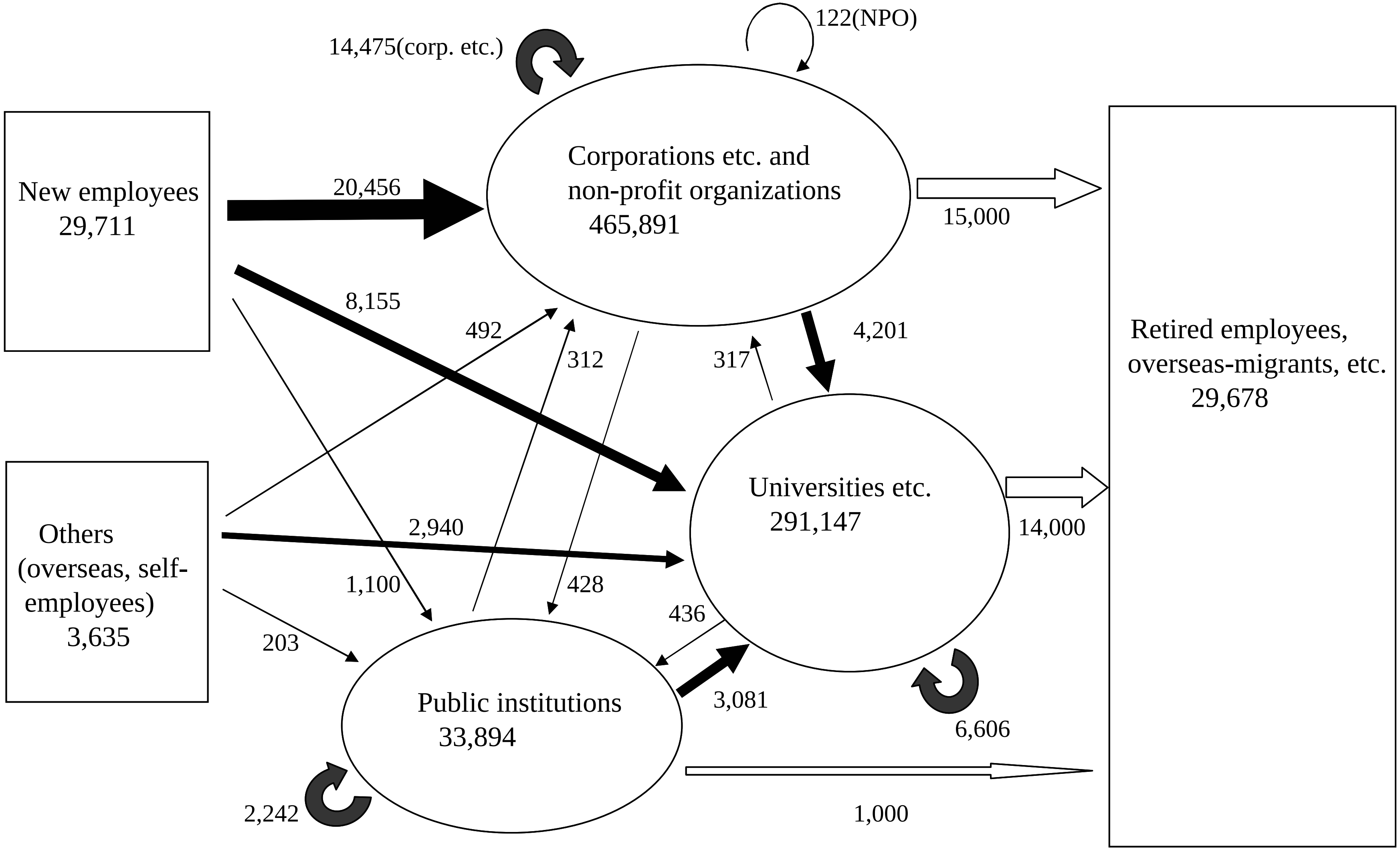


Figure 4 The Number of Notifications of Clinical Trials



Source: *Vision of Pharmaceutical Industry* (Ministry of Health, Labour and Welfare, 2002).

Figure 5 Mobility of Researchers in Japan (FY2004)



New recruitments, 65,566; Retirants and out-migrants, 29,678
Total number of researchers, 790,932

Data source: Bureau of Statistics, Ministry of Internal Affairs and Communications (complied by METI)

Source: *New Economic Growth Strategies 2006* (METI)