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UNIVERSITY-INDUSTRY COOPERATION AND TECHNOLOGY TRANSFER IN JAPAN COMPARED WITH THE UNITED STATES: ANOTHER REASON FOR JAPAN'S ECONOMIC MALAISE?†

ROBERT KNELLER*

1. INTRODUCTION

1.1. Purpose

Senior Japanese government officials have declared that improving university-industry cooperation is essential for Japan's economic revival.¹ Several researchers have pointed to problems associated with intellectual property ("IP") as factors hindering effective collaboration.² In addition, Japanese government and

* Robert Kneller (J.D. Harvard Law School 1980, M.D. Mayo Medical School 1984, M.P.H. Johns Hopkins 1986) worked in cancer research and technology transfer for nine years at the U.S. National Institutes of Health ("NIH") before becoming a Professor in the Department of Intellectual Property of the University of Tokyo's Research Center for Advanced Science and Technology ("RCAST") in 1998. His research compares university-industry cooperation in Japan, the United States, and other countries—particularly with respect to biomedical technologies, the ownership and transfer of intellectual property rights, and the role of startup companies.

The Author would like to thank the many persons in Japanese universities, government laboratories, government offices, and private companies who contributed information incorporated in this Article. He is grateful to Professors Akira Goto, Sadao Nagaoka, Sachiko Shudo, and John Walsh for helpful comments on drafts of this Article. He is indebted to the Abe Fellowship Program of the Japan Center for Global Partnership for enabling him to begin technology transfer research in Japan in 1997, and for continuing support for this research from the University of Tokyo and the Japanese Ministry of Education.

† Numerous sources noted herein have been compiled and translated by the Author.

¹ See Koji Omi, *Structural Reform of the Japanese Economy: A Science and Technology Driven Initiative*, Speech at the Royal Institute of International Affairs (May 1, 2002) ("[T]o activate R&D in Japan, reform of the nation's university system is essential."), available at <http://www.omi.or.jp>.

² See Mariko Yoshihara & Katsuya Tamai, *Lack of Incentive and Persisting Constraints: Factors Hindering Technology Transfer at Japanese Universities*, in *INDUSTRIALIZING KNOWLEDGE: UNIVERSITY-INDUSTRY LINKAGES IN JAPAN AND THE UNITED STATES*

business leaders note that one of the greatest barriers to collaboration is the "gap" between systems of collaboration and IP management in universities and industry.³ Heretofore, however, there has been no systematic analysis of ownership of inventions arising in Japanese universities and non-university government research institutes ("GRIs"). Nor, to the Author's knowledge, has anyone analyzed how the laws and policies determining ownership of inventions made in Japanese universities and GRIs have hindered public-private research cooperation and adversely affected certain high-technology industries, particularly the biomedical industry.

In addition, this Article analyzes related aspects of public-private research cooperation, including industry-sponsored research and the mobilization of human resources for projects relevant to industry. It draws upon the Author's more than five years of experience in a major Japanese university research center and his separate studies on Japanese biomedical startup companies and innovation in Japanese pharmaceutical companies. It also draws upon his compilation of available statistical data on university-industry cooperation and anecdotal case examples. Finally, it draws upon his experience in biomedical research, science policy and technology transfer in the U.S. National Institutes of Health ("NIH"). This background information, together with the analysis of the legal and institutional framework of the Japanese technology-transfer system that forms the core of

348, 352-353 (Lewis M. Branscomb et al. eds., 1999) (detailing the failure of Japanese universities to contribute to overall innovation and research and development ("R&D")); Christopher Heath, *Commercializing University Inventions in Japan*, 12 ZEITSCHRIFT FUER JAPANISCHES RECHT 1, 20 (2001) (examining the discrepancy between frequent commercialization of university research in the United States and the relative paucity of such commercialization in Japan). See also Robert Kneller, *Intellectual Property Rights and University-Industry Technology Transfer in Japan*, 26 SCI. & PUB. POL'Y 113, 115 (1999) [hereinafter Kneller, *Intellectual Property Rights*], available at <http://www.nsftokyo.org/rm99-08.html> (Report No. RM99-08) (positing that publicly funded Japanese inventions face obstacles to commercialization). A longer version is available in Robert Kneller, *Intellectual Property Rights and University-Industry Technology Transfer in Japan*, in INDUSTRIALIZING KNOWLEDGE: UNIVERSITY-INDUSTRY LINKAGES IN JAPAN AND THE UNITED STATES 307, 310-321 (Lewis M. Branscomb et al. eds., 1999).

³ See *San gaku kan renkei samitto kakudai* [Industry-University-Government Summit Meeting], NIKKEI KEIZAI SHINBUN, Nov. 23, 2001, at 13 (noting the results of a summit meeting of business leaders, including the Minister of State for Science and Technology Policy, where more collaboration between industry and academia is expected to bridge the "gap" in collaborative research and patents) (on file with author).

this Article, provides evidence that the system has harmed Japan's technical and economic progress, at least in biomedicine and perhaps in other high-technology fields.

Taken together, the U.S. and Japanese systems probably embody the entire possible spectrum of technology-transfer systems: state ownership, university or research institute ownership, and individual inventor ownership. Thus, the U.S. and Japanese experiences, viewed over the past thirty years, provide insights into the strengths and weaknesses of the entire spectrum of possible technology-transfer systems—bearing in mind that the larger institutional and social context also influences system efficacy. As many countries consider reforms to improve university-industry cooperation, this comparative perspective may be valuable. In particular, it provides a cautionary warning to any country that has adopted, or might consider adopting, a system of “public” ownership of publicly financed IP.

However, the legal framework of Japanese technology transfer is undergoing profound changes. This Article describes these changes, the unresolved issues, and the possible benefits and problems that will result.

Finally, having interviewed and advised Japanese startup companies and potential investors in these companies, the Author is aware of how uncertain foreign investors are of Japanese technology-transfer procedures and how this uncertainty is one factor inhibiting investment in academic-based Japanese startup companies. Therefore, he hopes that this Article will clarify this issue for such investors and promote mutually beneficial transnational cooperation involving Japanese startup companies.

1.2. Importance of Technology Transfer and Analytical Framework

In the United States in 1999, 64 billion USD of research and development (“R&D”) was performed outside of industry laboratories, mostly in universities and GRIs. This accounted for 26% of the 244 billion USD of total R&D performed that year in the United States. Japan's total R&D activity (15.2 trillion yen or about 95 billion USD in 1998)⁴ was second only to that of the United

⁴ For this and subsequent conversions of Japanese yen to U.S. dollars (USD), the Author used the OECD purchasing power indices (160 yen/USD in 1999) instead of market exchange rates (approximately 120 yen/USD in 1999). The former are more stable than the latter and provide a more accurate approximation of purchasing power in most R&D fields. NAT'L SCI. BD., 2 NAT'L SCI. FOUND.,

States. Twenty-nine percent of this activity occurred outside of industry laboratories. In Germany, the United Kingdom, and France non-industry R&D accounts for 31%, 34%, and 38%, respectively, of total R&D.⁵ The discoveries that emerge from universities and GRIs usually are not ready for public or commercial use, even though some may have the potential to be developed into useful products or services. More development is often needed—especially in the case of inventions arising in certain fields such as biomedicine. However, most universities and GRIs are not able to commercialize early-stage discoveries. The private sector can, but there must be an effective system to transfer information to industry, and there must be incentives for industry to develop and commercialize discoveries originating in academic laboratories—the term that this Article uses henceforth to refer collectively to universities, GRIs, and academic medical centers.

At the same time, university-industry cooperation should enhance rather than undermine the basic goals of universities: namely education and curiosity-driven expansion of knowledge to be made available to the public. The fundamental goal of technology transfer is to ensure the development of early-stage discoveries for the public benefit, while enhancing the basic goals of academic laboratories. The central issue underlying this Article is what types of legal frameworks provide the foundation for effective technology transfer and public-private R&D cooperation.

Important mechanisms of cooperation and technology transfer in both the United States and Japan include: (1) publication of information; and (2) employment and transfers of R&D personnel.⁶ However, these modes of transfer usually do not involve direct interaction between industry and academic research centers. Direct interactions usually occur under the following mechanisms:

- 1) *consultation or advisory agreements* between individual academic researchers and companies;
- 2) *material transfer agreements* of unpatented technologies for

SCIENCE AND ENGINEERING INDICATORS A4-2 (2002), available at <http://www.nsf.gov/sbe/srs/seind02/pdfstart.htm>.

⁵ *Id.* at A4-80 (2002).

⁶ Akira Goto & Akiya Nagata, *Technology Opportunities and Appropriating the Returns from Innovation: Comparison of Survey Results from Japan and the United States*, NAT'L INST. SCI. AND TECH. POL'Y ("NISTEP") REPORT NO. 48 (1997) (in Japanese), available at http://wakame.econ.hitu.ac.jp/~sample/kyoukan/EN_goto.htm.

- early-stage or non-commercial research;
- 3) *licenses or assignments* of existing technologies;
- 4) *collaborative or sponsored research agreements* to develop new information or technologies; and
- 5) formation of *start-up companies*, usually financed by private venture capital or government grants.

Only these direct mechanisms, in particular the latter three, permit *contractual guarantees* that:

- a) IP rights will be transferred to industry;
- b) the recipients of technology will make best efforts to develop the technologies; and
- c) the academic centers will share in future commercial benefits.

Concerning the transfer of IP rights, transfers of exclusive rights are often essential if a company is to take the risk to develop early-stage academic discoveries. This is particularly true in industries such as biotechnology and pharmaceuticals, where much development work is necessary before a new product can be marketed and yet the final product can be easily copied. Exclusive IP rights are one way to prevent copying by competitors. Exclusive IP rights can also be important for university startup companies to obtain private funding to develop early-stage, commercially risky academic discoveries. Therefore, in the case of promising academic inventions requiring expensive development, especially by startup companies, one or more of the latter three forms of technology transfer (licenses, assignments, collaborative research-sponsored agreements, or the formation of startup companies) must usually be used to ensure that appropriate incentives exist for academic researchers, academic administrations, and private investors to take the necessary steps to ensure that such inventions are developed.

Appropriate incentives are the key to making the technology transfer process work effectively, especially:

- 1) incentives for *academic researchers* to be aware of the commercial potential of their discoveries and to (a) cooperate with offices that are responsible for managing and commercializing their discoveries, or (b) initiate effective steps on their own to ensure that the commercial potential of their discoveries is realized, while preserving the primacy of their academic obligations;
- 2) incentives for *officials in academic institutions* to try to ensure that discoveries with commercial or public health potential

are effectively developed, again while preserving the primacy of academic objectives and values; and

- 3) incentives for *private companies* to work with academic officials and researchers to ensure that discoveries with commercial or public health potential are effectively developed.

The main focus of this Article is the legal framework for technology transfer and how it shapes incentives to make technology transfer occur effectively. The Article will emphasize the laws and regulations governing ownership and transfer of IP rights under mechanisms mentioned above—especially how these laws influence incentives to ensure that promising academic discoveries are developed into beneficial products and services.

Of course, effectiveness of academic-industry cooperation depends upon other factors besides the laws governing ownership and transfer of IP rights, such as:

- national expectations about the fundamental purpose of academic research;
- national R&D budgets, funding mechanisms, and project selection criteria;
- career incentives for academic and industry researchers;
- the sociology of academic and corporate R&D;
- corporate business strategies and management practices; and,
- capital markets and various tax laws.

This Article will address these factors briefly to the extent that they influence the effectiveness of the technology-transfer systems in Japan and the United States.

1.3. Article Organization

Section 2 of this Article provides an overview of the U.S. system of academic-industry cooperation. This provides a comparative framework for the analysis of the Japanese system in Section 3, as well as the conclusions in Section 4. However, readers who are familiar with the U.S. system, or who are short of time, may skip Section 2. Both Sections 2 and 3 analyze technology transfer, first from the perspectives of universities and academic medical centers, and then from GRIs. The subsections will discuss: first, sponsored research agreements with private companies; second, assignments and licenses, particularly of government-funded inventions; third, consulting and other outside work; and fourth, formation of

startup companies. Appendix 1 describes the methods used to estimate in Table 1 the amount of funding under the various mechanisms to support R&D in universities. Appendix 3 briefly discusses technology transfer via Material Transfer Agreements ("MTAs").

2. OVERVIEW OF THE U.S. SYSTEM

2.1. U.S. Universities

2.1.1. *Sponsored Research Agreements*

For the purposes of this Article, "sponsored research" encompasses terms such as "contract research," "commissioned research," "collaborative research agreements," and "joint research." The basic concept is that a company supports academic research by providing various resources (such as money, research personnel, data, equipment, and proprietary medicines), and in return, receives from the academic institution: (1) information; and (2) in some instances, academic research personnel and/or IP rights in discoveries arising from the research it supports.

2.1.1.1. *IP Considerations*

In the United States, there are relatively few constraints on the freedom of universities and academic medical centers (henceforth collectively referred to as "universities") to negotiate such agreements with companies. As a general rule, U.S. universities own all work products of their employees, with the exception of copyrightable non-software works where ownership sometimes remains with the Authors. This is a result of two factors:

- 1) Universities are increasingly asserting standard employers' rights to require their faculty and all other employees to assign their work products. With respect to potentially patentable inventions, this process was begun by the Massachusetts Institute of Technology ("MIT") in the 1930s and is now a standard practice.⁷ With respect to copyrightable

⁷ Henry Etzkowitz, *Knowledge as Property: The Massachusetts Institute of Technology and the Debate over Academic Patent Policy*, 32 MINERVA 383, 383-421 (1994) (discussing how MIT began the process of asserting employer rights over employee work products historically). See also Robert Kneller, *Technology Transfer: A Review for Biomedical Researchers*, 7 CLINICAL CANCER RESEARCH 761, 762 (2001)

works, the Copyright Act of 1976 enabled universities to apply the "work-for-hire" doctrine⁸ and thus claim authorship over many of their employees' written works.⁹ Today, most universities assert ownership over work-related computer programs, laboratory research data, and other work products that rely substantially on university resources, or on grants or contracts to the university from outside sources.¹⁰

- 2) The 1980 Bayh-Dole amendments to U.S. patent law¹¹ and the 1987 implementing regulations,¹² permit universities to claim worldwide ownership rights over inventions made under U.S. government grants and contracts. Prior to these amendments, there was no uniform policy regarding IP rights to discoveries made with U.S. government support. In general, however, IP rights vested in the government unless the funding agency waived its rights,¹³ and funding agencies could only issue nonexclusive licenses absent special justification.¹⁴ Under the Bayh-Dole Act and Regulations, the U.S. government retains some residual

[hereinafter Kneller, *Technology Transfer*] (discussing employers' contractual right to require assignment of their employees' work product), available at <http://clincancerres.aacrjournals.org/cgi/content/full/7/4/761>.

⁸ 17 U.S.C. § 101 (2000).

⁹ ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, INC. (AUTM), AUTM TECHNOLOGY TRANSFER PRACTICE MANUAL IV, § 2.3.9.E. (1994) (discussing ownership issues for academic institutions and noting that if the work-for-hire doctrine is considered to rule in relationship to a scholarly work, there must be a written, signed transfer to the faculty member).

¹⁰ See Jerome H. Reichman, *Overlapping Proprietary Rights in University-Generated Research Products: The Case of Computer Programs*, 17 COLUM.-VLA J. L. & ARTS 51, 51-125 (1992) (providing an overview of development of U.S. proprietary rights with an emphasis on commercial university research). See also TECHNOLOGY LICENSING OFFICE, MASSACHUSETTS INSTITUTE OF TECHNOLOGY ("MIT"), GUIDE TO THE OWNERSHIP, DISTRIBUTION AND COMMERCIAL DEVELOPMENT OF MIT TECHNOLOGY (1999) (outlining MIT's intellectual property rights policy), available at <http://web.mit.edu/tlo/www/guide.toc.html>.

¹¹ Bayh-Dole Act, 35 U.S.C. §§ 200-212 (1994).

¹² 37 C.F.R. § 401 (2002).

¹³ See Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1671, 1671-1695 (1996) (discussing the history of the government-owned patent policy in the United States). See also Kneller, *Technology Transfer*, *supra* note 7, at 762 (describing technology transfer procedures).

¹⁴ 45 C.F.R. § 6.3 (repealed) with respect to licensing of Department of Health, Education, and Welfare inventions.

rights over such inventions, the funding agencies must approve assignments by universities, and certain restrictions apply to exclusive licenses.¹⁵ Nevertheless, since 1980, universities have enjoyed substantial control over the fruits of federally funded R&D conducted by their employees – funding that accounts for 58% of the total R&D budget of U.S. universities.¹⁶ Since the late 1970s, patenting and licensing by universities have increased dramatically.¹⁷

Two additional aspects of the Bayh-Dole regulations¹⁸ have reinforced the tendency of universities to require assignment of all of their employee's inventions, even though Bayh-Dole does not require such assignment:

- a) the comprehensive reporting requirements; and
- b) the cumbersome procedures for inventors to retain ownership.

Universities must establish procedures to ensure that university employees inform their universities of government-funded inventions soon after they are made and of any public disclosures of such inventions. Universities must report this information to the funding agencies and inform the agencies in a timely manner whether they will apply for U.S. and foreign patents.¹⁹ If a university decides not to apply for patents, these rights devolve to the funding agency – not to the individual inventors. After consultation with the university, the funding agency may grant requests for the inventors to retain rights.²⁰ The Author's experience working in technology transfer at NIH suggests that expeditious procedures for funding agencies to waive their rights so that inventors can retain ownership still have not been worked out. Therefore, the stringent Bayh-Dole reporting requirements, coupled with cum-

¹⁵ Kneller, *Technology Transfer*, *supra* note 7, at 765-768. See discussion *infra* § 2.1.2. Licensing.

¹⁶ NAT'L SCI. BD., *supra* note 4, at A5-2.

¹⁷ See David Mowery et al., *The Effects of the Bayh-Dole Act on U.S. University Research and Technology Transfer*, in *INDUSTRIALIZING KNOWLEDGE: UNIVERSITY-INDUSTRY LINKAGES IN JAPAN AND THE UNITED STATES* 269, 275 (Lewis M. Branscomb et al. eds., 1999) ("The Bayh-Dole Act is contemporaneous with a sharp increase in U.S. university patenting and licensing activity."); Kneller, *Technology Transfer*, *supra* note 7, at 762 (analyzing the past and present scope of technology transfer in universities).

¹⁸ 37 C.F.R. § 401 (2002) (implementing 35 U.S.C. §§ 200-212 (2000)).

¹⁹ 37 C.F.R. § 401.14(c), (f) (2002).

²⁰ 35 U.S.C. § 202(d) (1994).

bersome procedures to allow inventors to retain rights, has led all major U.S. research universities to require assignment of all potentially patentable inventions by their employees, at least those made with U.S. government funds.²¹

As a result of ownership of IP vesting in universities, universities are relatively free to negotiate transfers of IP arising from the use of the corporate-sponsored research funds, even when these funds are mixed with government funds. Because industry-sponsored contract research amounts to only about 7% of the total university R&D budget (and only 12% of the federal contribution),²² most universities apply the Bayh-Dole technology management procedures, discussed *infra* under "Licensing," even to inventions that do not arise under government funding. In particular, even in the case of inventions arising solely under industry sponsorship, universities often will not assign such inventions to the sponsors, although they will negotiate exclusive licenses and frequently let the sponsors manage patent prosecution.

Most universities have established technology management or technology licensing offices ("TLOs"),²³ which have become the focal point of their technology transfer activities, although some universities maintain separate offices to deal with sponsored research contracts.

2.1.1.2. Mobilizing Human and Material Resources

Universities can use corporate funds to employ a wide range of research personnel including secretaries, technicians, Ph.D. stu-

²¹ Some universities have elected not to assert the maximum number of possible rights. For example, the University of Wisconsin lets faculty own inventions that do not arise under U.S. government-funded projects. Also, points of debate remain, for example, whether graduate students can retain ownership of their inventions, particularly if their stipends are paid by a source other than the university or government grants. Universities' policies on this issue vary. Finally, the way in which universities assert ownership over inventions varies. Some universities require new employees to sign a formal agreement prospectively assigning to the university all rights, title, and interest in any future work-related inventions. Others wait until they receive notification from the inventor and then request the inventor to execute an assignment agreement. For an informative survey of intellectual property ("IP") management by U.S. universities, see Jerry Thursby et al., *Objectives, Characteristics, and Outcomes of University Licensing: A Survey of Major U.S. Universities*, 26 J. TECH. TRANSFER 59, 59-72 (2001).

²² NAT'L SCI. BD., *supra* note 4, at A-312.

²³ See *infra* note 189 for the origin of this abbreviation.

dents, and postdoctoral researchers.²⁴ Even tenured faculty members in science and engineering departments in most U.S. universities are expected to draw part of their salaries from research grants or contracts from industry, government, or private foundations²⁵ — i.e., from “soft-money” sources.²⁶ In addition, universities are free to demand that companies pay the indirect costs associated with the research they support. The percentage of such overhead costs varies from university to university, but is often above 50% of direct project costs.²⁷ In most prestigious private universities, faculty members are expected to pay for a significant proportion of overhead costs (including libraries, computer facilities, security, main-

²⁴ Support for Ph.D. students and postdoctoral researchers is often designated as “fellowships,” “traineeships,” “research assistantships,” “teaching assistantships,” “work-study,” and so on, yet less than 40% of science and engineering Ph.D. students in the United States are self-supported. NAT’L SCI. BD., *supra* note 4, at 6-28 to 6-41. In the major research universities, this percentage is lower and support usually covers tuition plus living expenses. E-mail from Jon Miller, Faculty Member, Northwestern University, to Author (Oct. 10, 2001) (on file with author).

²⁵ For example, in a major state university, medical school faculty who are M.D.s cover a quarter of their salaries on average from grants and contracts, while non-M.D.s cover 40-50% of their salaries from such sources. For engineering faculty, the figure is about 40% when factoring in summer months. For biology, chemistry, and physics faculty, salaries are guaranteed for the normal academic year, but they must draw 100% of their summer-month salaries from outside sources. E-mail from Fawwaz Ulaby, Vice-President for Research, University of Michigan, to Author (Sept. 25, 2001) (on file with author).

²⁶ This does not mean that science and engineering faculty can arbitrarily designate a portion of their grant funds as personal compensation. Grant and contract payments from government and industry are almost always made to the university, not to individual researchers. Generally, for assistant professors and recently promoted associate professors in similar departments in equivalently ranked universities, salaries are approximately equivalent nationwide. Even for more senior faculty, whose salaries are decided at the institution or department level on the basis of teaching, scholarship, and service, outside research support is not directly factored into most faculty compensation formulas. See H. Roland Weistroffer et al., *A Merit Pay Allocation Model of College Faculty Based on Performance Quality and Quantity*, 20 ECON. EDUC. REV. 41, 41-49 (2001). However, outside research support usually leads to an increase in graduate students, scholarly output, and management responsibilities, all of which can justify increased compensation. Furthermore, success in obtaining “soft money” is often regarded as an indication of level of scholarship and productivity, and annual salary increments (as well as promotions) often reflect success in obtaining “soft money,” particularly peer-reviewed grants from respected institutions such as NIH, National Science Foundation (“NSF”), and the Howard Hughes Medical Research Foundation.

²⁷ Overhead rates are often established or verified by government auditors, since government agencies must also pay overhead when they fund research in universities.

tenance, and utilities) from "soft money."

2.1.2. *Licensing*

This Subsection deals with transfers of existing technologies as opposed to those that may arise in the course of cooperative research. In addition to licenses, it covers assignments—complete transfers of ownership rights. As noted in Section 2.1.1.1, the right of universities to own and license work-related inventions of their employees derives from the employer-employee relationship and the Bayh-Dole law and regulations.

The Bayh-Dole regulations also set forth specific obligations related to licenses of university inventions made with government support:

- 1) Universities and other nonprofit organizations may not assign U.S. rights to such inventions without approval of the funding agency.²⁸ Consequently, assignments are rare and exclusive license rights are usually the strongest rights that are transferred.
- 2) Inventors must receive a share of royalty income.²⁹
- 3) The balance of any royalties, after payment of administrative expenses, must be used for the support of scientific research and education.³⁰
- 4) Universities must make efforts "reasonable under the circumstances" to attract small business licensees and to give licensing preference to small businesses.³¹
- 5) An exclusive licensee of the U.S. rights to an invention must agree to manufacture substantially in the U.S. products made using the invention.³²
- 6) Universities must report annually to the funding agencies on the development status of inventions including royalties

²⁸ 37 C.F.R. § 401.14(k)(1) (2002).

²⁹ 37 C.F.R. § 401.14(k)(2) (2002).

³⁰ 37 C.F.R. § 401.14(k)(3) (2002).

³¹ 37 C.F.R. §§ 401.7, 401.14(k)(4) (2002). The following are criteria to qualify for "small business" status: independent ownership and operation (i.e., not affiliated with a larger organization); total employees (including those of any affiliates) not exceeding 500; not dominant in its field of operation; principal place of business located in the United States; at least 51% owned (or in the case of a company whose stocks are publicly traded, at least 51% of its voting stock owned) by U.S. citizens or permanent resident aliens. 13 C.F.R. § 121.4 (2002).

³² 37 C.F.R. § 401.14(i) (2002).

received and date of first commercial sale.³³

- 7) The government must receive a nonexclusive, nontransferable, irrevocable royalty-free license in order to practice the invention throughout the world or to have the invention practiced on its behalf.³⁴
- 8) The government can require third-party licensing if the university, or its licensee, is not taking effective steps to develop the invention or such action is necessary to meet health or safety needs.³⁵ The government has never fully exercised these "march-in rights." To do so would be difficult and would require many procedural steps designed to protect the interests of universities and their licensees.
- 9) U.S. patent applications must acknowledge the government support and the government's residual rights.³⁶

Details concerning these obligations and the process and strategy of licensing by university TLOs, are set forth in a separate publication by the Author available online.³⁷ This publication also contains summary statistics on the extent of university technology transfer. More detailed licensing statistics are available in publications by the Association of University Technology Managers ("AUTM").³⁸

It is often considered good practice for universities to include "due diligence" or "technical benchmark" conditions in exclusive licenses to encourage licensees to make best efforts to develop the university inventions. For example, an exclusive license may automatically expire after one year unless the licensee pays an annual renewal fee, which often increases each year. In the case of pharmaceutical-related inventions, it is common to have technical conditions such as:

- the exclusive licensee must develop two analogs of the parent compound with greater bioavailability (for example, solubility) within one year of license execution; or
- within three years of execution, the licensee must complete

³³ 37 C.F.R. §§ 401.8, 401.14(h) (2002).

³⁴ 37 C.F.R. § 401.14(b) (2002).

³⁵ 37 C.F.R. §§ 401.6, 401.14(j) (2002).

³⁶ 37 C.F.R. §§ 401.6, 401.14(f)(4) (2002).

³⁷ Kneller, *Technology Transfer*, *supra* note 7, at 762-69.

³⁸ See, e.g., ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, INC. (AUTM), AUTM LICENSING SURVEY: FY 1998 (1999) (collecting data related to the licensing activity of universities and research institutions).

animal testing necessary to apply for Food and Drug Administration ("FDA") approval to begin human trials.

If these conditions are not met, the license can automatically terminate. In practice, however, universities usually will renegotiate such conditions if they believe that their licensees are making good faith efforts to develop the technologies—not simply denying access to competitors. Also, it is difficult for a licensor to litigate successfully to terminate a license on the grounds that technical benchmark conditions have not been met.

Nevertheless, licensees sometimes argue that a decision to suspend development of a licensed technology may be made on the basis of sound business considerations after many years of in-house R&D, and it would be unfair if the university could then license the same technology to a competitor.³⁹ Therefore, licensees sometimes complain that their inability to obtain outright assignments of university IP puts early-stage university discoveries at a disadvantage in relation to in-house discoveries.

However, the most significant controversies today surrounding university patenting and licensing are not whether universities have sufficient leeway and incentives to manage and commercialize their inventions, but rather whether they have too much freedom to act entrepreneurially. It has been suggested that universities are patenting too many early-stage technologies and then licensing their rights exclusively to private companies. These private companies (often startup companies from the universities) may then charge sublicensees excessively high royalties, or charge excessively high prices for their products and services. Additionally, the universities may themselves demand excessively high royalties from exclusive licensees. Even if universities and their exclusive licensees do not behave avariciously, the explosion of IP claims to early-stage discoveries whose usefulness is often limited to research (i.e., "research tools") may dissuade some university laboratories or companies from pursuing research in a particular area, either because they are afraid of infringement suits or because they believe that the transaction costs of negotiating licenses with numerous IP owners would be too costly. Even if they are willing

³⁹ Such concerns are raised most often by pharmaceutical and biotechnology companies. They assert that at the start of a long, risky development project in a particular therapeutic area, they tend to give priority to lead compounds discovered in-house, even though there may be equally promising compounds in-licensed (or available for in-licensing) from universities.

to endure these transaction costs, the price of the final product may be burdensome for end users because high royalties have to be paid to use the many patented technologies incorporated in the final product (i.e., "royalty stacking").

In addition, it has been suggested that an increased emphasis on patenting, stock options in startup companies, and the prospect of high license royalties or large industry funding for sponsored research may shift the focus of research to more applied, commercially relevant fields and may also lead university researchers to be more secretive – thus distorting core academic goals and values.

This Article cannot address these issues in depth. However, a recent study suggests that while patenting of early-stage inventions by universities has contributed to a sharp rise in patent applications and has made the landscape of often overlapping patent claims much more complex. It is rare for either commercial or academic research to be blocked by such claims,⁴⁰ except in a few areas, notably genetic testing, where a significant number of clinical laboratories and geneticists report foregoing development of a new genetic test because the genetic sequence or a similar test is already patented or licensed.⁴¹ Also, a number of recent steps by private companies, the U.S. Patent and Trademark Office ("PTO"), and government funding agencies are reducing the likelihood that IP issues will stymie innovation.⁴²

⁴⁰ John P. Walsh et al., *Working Through the Patent Problem*, 299 SCI. 1021, 1021 (2003) ("[A]lmost none of our respondents reported worthwhile projects being stopped because of issues of access to IP rights to research tools."). For a more complete analysis, see John P. Walsh et al., *Science, Technology, and Economic Policy Board of The National Academies, The Patenting of Research Tools and Biomedical Innovation* (2001), at http://www7.nationalacademies.org/step/walsh_presentation.ppt.

⁴¹ Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 3-8 (2003). See also Jon Merz, *Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Practice*, 45 CLINICAL CHEMISTRY 324, 326-28 (1999) (finding that disease gene patents are used to monopolize medical services exclusively for large clinical laboratories); *Oversight Hearing on Gene Patents and Other Genomic Inventions Before the Subcomm. on Courts and Intellectual Prop. of the House Comm. on the Judiciary*, 106th Cong., 2d Sess. (2000) (statement of Jon Merz, Assistant Professor of Bioethics, University of Pennsylvania), at <http://www.house.gov/judiciary/merz0713.htm>.

⁴² *Id.* For example, the pharmaceutical company Merck is funding gene sequencing and identification research (largely at Washington University) and making the results public. NIH and the Department of Energy ("DOE") require that all information obtained from high throughput sequencing under the Human Genome Project be deposited immediately into public databases. Both of these steps diminish the chance that patents can be obtained on the genes identified by these

The Principles and Guidelines on Obtaining and Disseminating Biomedical Research Resources, issued in 1999 by the NIH, address the concern that universities are issuing too many exclusive licenses for government-financed discoveries, thereby restricting access for both private companies and other academic researchers.⁴³ These guidelines strongly recommend that universities license *non-exclusively* inventions made under NIH funding whose main utility is as "research tools." If an exclusive license to a private company is necessary in order to ensure development of a research tool, then the university should negotiate license terms that obligate the licensee company to make the final product readily available to the university research community.⁴⁴

As for the other concerns, there is little clear evidence that the focus of university R&D has shifted significantly towards applied research, probably because peer-reviewed, government-funded support for basic research continues to be the dominant form of R&D support.⁴⁵ There is evidence to suggest that concerns about IP have increased secrecy,⁴⁶ although the alternative may be even more secrecy if professors protect their commercially valuable discoveries by treating them as secrets. Also, a recent study suggests that the main reason biomedical researchers withhold data relates

projects. The United States Patent and Trademark Office ("PTO") has issued stricter guidelines on how to satisfy the utility and written description requirements of U.S. Patent Law. 66 Fed. Reg. 1092, 1099 (Jan. 5, 2001), *available at* <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>. It is also encouraging the formation of patent pools to reduce the burden of stacked royalties and transaction costs. U.S. PAT. & TRADEMARK OFF., PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? (2000), *at* www.uspto.gov/web/offices/pac/dapp/opla/patpoolcover.html.

⁴³ NAT'L INST. HEALTH, THE PRINCIPLES AND GUIDELINES ON OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES (1999), *available at* http://www.nih.gov/od/ott/Rtguide_final.html/.

⁴⁴ For an analysis of these guidelines, see Kneller, *Technology Transfer*, *supra* note 7, at 766-67.

⁴⁵ Mowery et al., *supra* note 17; David Blumenthal et al., *Relationships Between Academic Institutions and Industry in the Life Sciences – An Industry Survey*, 334 NEW ENG. J. MED. 368, 372 (1996) ("Although it is a substantial complement to federal support, industrial sponsorship remains small as compared with NIH funding."); JERRY THURSBY & MARIE THURSBY, WHO IS SELLING THE IVORY TOWER? SOURCES OF GROWTH IN UNIVERSITY LICENSING 18-19 (Nat'l Bureau of Econ. Research, Working Paper No. 7718, 2000), *available at* <http://papers.nber.org/papers/w7718.v5.pdf>.

⁴⁶ David Blumenthal et al., *Academic-Industry Research Relationships in Genetics: A Field Apart*, 16 NATURE GENETICS 104, 106-07 (1997); David Blumenthal et al., *Withholding Research Results in Academic Life Science: Evidence from a National Survey of Faculty*, 277 J. AM. MED. ASS'N. 1224, 1226-27 (1997).

more to the effort needed to produce the requested information and the need to protect the work of graduate students and junior faculty than the need to protect IP rights or to honor the requirements of an industrial sponsor.⁴⁷

2.1.3. Consulting

There has been a long tradition of U.S. university faculty consulting for private industry. However, the Author is not aware of a systematic study of the frequency and type of consulting arrangements between university faculty and industry, much less their impact on industrial innovation and university research and education. Available data suggest that a large proportion of senior biomedical university researchers engage in consulting, although the nature of the consulting ranges from an occasional paid lecture to more than forty paid consulting days per year in addition to a directorship position and equity ownership.⁴⁸

University policies vary concerning what types of consulting relationships are acceptable as well as policies on disclosure and approval. One recent study that examined consulting and conflict-of-interest policies in ninety-seven universities found considerable variation concerning disclosure obligations and prohibited activities.⁴⁹ The Author's own review of a much more limited number of policies relating specifically to consulting seemed to show stricter

⁴⁷ Erik Stokstad, *Data Hoarding Blocks Progress in Genetics*, 295 SCI. 599, 599 (2002).

⁴⁸ Howard Hughes Medical Institute ("HMMI") is one of the few institutions that requires pre-approval of all consulting agreements. In 2000, 56% percent of HMMI's 346 investigators were engaged in at least one type of consulting relationship. Thomas R. Cech & Joan S. Leonard, *Conflicts of Interest – Moving Beyond Disclosure*, 291 SCI. 989, 989 (2001). A study of University of California – San Francisco ("UCSF") biomedical researchers required to disclose financial interests in companies planning to sponsor their research gives some clues as to the nature of such relationships. Among 488 disclosures by UCSF researchers (mostly principal investigators or other senior researchers) between 1980 and 1999, about 32% involved an occasional speaking engagement, 33% paid consulting, and 32% held a paid position on a Scientific Advisory Board or a Board of Directors. Elizabeth A. Boyd & Lisa A. Bero, *Assessing Faculty Financial Relationships with Industry: A Case Study*, 284 J. AM. MED. ASS'N 2209, 2209-14 (2000). Since this distribution is only for consulting on behalf of prospective research sponsors, it may be more biased towards "high involvement" activities than the distribution for consulting relationships as a whole. The UCSF study found that 14% of the disclosures reported equity ownership in the prospective sponsor. *Id.*

⁴⁹ Mildred K. Cho et al., *Policies on Faculty Conflicts of Interest at U.S. Universities*, 284 J. AM. MED. ASS'N 2203, 2203-08 (2000).

limits and more uniformity than suggested by the ninety-seven universities' study, although the Author can make no claims as to the representativeness of his sample.⁵⁰ Based on this small sample, the Author's knowledge of policies in other universities, and the above referenced study of policies in ninety-seven universities, the following seem to be commonly true regarding consulting:

- One day per week is the maximum time a faculty member can devote to outside consulting;
- Consulting activities must be reported at least annually to at least the department head (this usually occurs after the relationship has begun);
- Engaging in research sponsored by a company with which the faculty member has a paid consulting position is prohibited;
- Holding a senior management position in a company is usually prohibited unless the faculty member takes a leave of absence from the university or departs from full-time status;
- Transfer or compromise of IP that ought to belong to the university is prohibited in the course of consulting activities;
- Limits on the amount of income that can be earned via consulting are rare (but Johns Hopkins does require permission for regular outside income)—some universities even bar collecting data on the amount of outside income; and

⁵⁰ For this review, the Author reviewed the policies of two private and two state universities trying to choose one institution from each category with a reputation of being relatively permissive, and likewise, one institution from each category with the a reputation of being relatively restrictive concerning consulting and faculty ties with industry. Thus, he reviewed the conflict-of-interest and consulting policies of MIT, Johns Hopkins University (including those specific to the medical school), the University of California, and the University of Washington, available at <http://www.mit.edu/afs/athena.mit.edu/org/p/jhursearch.jhu.edu/ott/Inventors/conflict.asp/>; http://www.hopkinsmedicine.org/research/policies_conflict.html, <http://www.ucop.edu/ott/consult.html>; and <http://www.cs.washington.edu/faculty/facsenate/>, respectively. Among these four policies, the Johns Hopkins University conflict-of-interest and consulting policy was unique in not specifically excluding any types of activities, but instead requiring that a relatively wide range of activities be approved at the department head level and sometimes also by the Medical School's Conflict of Interest Committee. Only MIT's policies specifically addressed graduate students participating in consulting and other outside activities. The University of Washington's policies had more absolute prohibitions against certain activities (e.g., holding a line management position in an outside company) than did the others.

- It is rare to have more stringent obligations, including disclosure requirements, concerning consulting relationships in companies that have an interest in the outcome of clinical trials.

On the other hand, the policies often vary with respect to the following issues, with some institutions not even requiring notification:

- the extent to which university facilities can be used in support of consulting activities;
- the ability of faculty members and the graduate students whom they supervise to work in the same outside company;
- the need for consulting activities to be approved in advance, and the level of approval required (department heads, dean, provost, etc.);
- stock ownership; and,
- membership on scientific advisory boards.

The main purpose in discussing these issues is to lay the basis for the later discussion of consulting and startup company formation by Japanese universities. As will be shown, the current official Japanese policies regarding outside work are, on the surface, not extremely different from the "typical" U.S. guidelines.

In summary, it appears that consulting is an important factor in a two-way exchange of information between universities and industries, although to the Author's knowledge, this exchange has not been carefully analyzed. Also, consulting has probably greatly facilitated the formation of startup companies and their viability, although this process also has not been thoroughly analyzed. Finally, consulting has given rise to complex and serious conflict-of-interest issues, some of which will be discussed below.

2.1.4. *Start-up Companies*

For the purpose of this paper, startup companies are considered to be recently formed independent companies based upon university discoveries. Usually such companies are exclusive licensees of patents or copyrights owned by a university, and their business plans are based upon the development or commercialization of these or related technologies. University faculty or recent graduate students often assume an important role as founders, advisors or lead scientists.

Currently 350 to 400 startup companies are formed from U.S.

academic institutions each year. About 3000 have been formed since 1980, of which about 68% are still operational.⁵¹ In biomedicine and biotechnology, there were approximately 1300 companies in 1999, 300 of which had publicly traded stock.⁵² The vast majority of these biotechnology companies probably had close links at their founding with academic institutions.

The vast majority of investment capital for startups comes from private sources (angel investors, venture capital funds, and established companies). Particularly in drug development and other biomedical fields, venture capital-financed startup companies play a vital role in developing university discoveries to the point where they become attractive to larger, more established companies. However, in order for biomedical startups to attract private investment, they need clear, exclusive, and transferable IP rights to their core technologies.

Governments, and sometimes, universities themselves, provide more limited alternative sources of "capital." Most universities can now take a limited equity stake (usually not more than 10 percent) in some of their startups in lieu of up-front royalties when the universities exclusively license core technologies to these startups. In addition, some universities have investment funds, which they can use to direct investment in their startups. Under the U.S. government's Small Business Innovative Research ("SBIR") Program, startups and other small businesses can receive peer-reviewed, competitively allocated, project-specific research support of up to \$750,000.⁵³ SBIR funds often help to bridge the gap between academic research funding, primarily from government agencies such as NIH, National Science Foundation ("NSF"), and the Department of Defense, and private investment.

2.1.5. *Conflicts of Interest*

The main constraints on industry support for university R&D arise from concerns about conflicts of interest on the part of corporate-funded university researchers—and the related need to pre-

⁵¹ ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS ("AUTM"), AUTM LICENSING SURVEY: FY 2000 SURVEY SUMMARY 14-15 (2002).

⁵² ERNST & YOUNG, CONVERGENCE: THE BIOTECHNOLOGY INDUSTRY REPORT 14 (2000), available at <http://www.ey.com/industry/health>.

⁵³ Federal agencies with annual R&D budgets exceeding \$100 million must set aside 2.5% of these budgets to Small Business Innovative Research ("SBIR") grants. 15 U.S.C. § 638 (2003).

serve academic freedom, scientific objectivity, and the primacy of academic goals.

A full discussion of conflict-of-interest principles and practices is beyond the scope of this Article.⁵⁴ A number of federal agencies have regulations that establish minimal financial disclosure and basic procedural requirements for universities and medical centers applying for grants or contracts. For example, regulations issued in 1995 by the U.S. Public Health Service ("PHS") require that any institution submitting an application for a grant or contract to a PHS agency, such as the NIH, have first obtained a report from each prospective investigator listing the investigator's "significant financial interests" that (a) would reasonably appear to be affected by the research for which PHS funding is sought, or (b) are in entities that would reasonably appear to be affected by the research. "Significant financial interests" include salary or consulting fees from companies totaling over \$10,000 annually, stock holdings over \$10,000, patents, and royalties. If the institution receives the award, it must report to the funding agency the existence of any conflicting interest and assure the agency that the conflict "has been managed, reduced, or eliminated."⁵⁵ Other agencies have similar disclosure policies.⁵⁶ All of these federal regulations or guidelines leave universities considerable discretion regarding how to manage conflicts of interest and commitment. The Association of American Universities has recently issued more comprehensive model guidelines.⁵⁷

In order to avoid conflicts of interest that might endanger humans participating in biomedical research, the Association of

⁵⁴ See Peter J. Harrington, *Faculty Conflicts of Interest in an Age of Academic Entrepreneurialism: An Analysis of the Problem, the Law and Selected University Policies*, 27 J. C. & U. L. 775 (2001) (offering a recent analysis of conflicts of interest law in an academic setting).

⁵⁵ 42 C.F.R. §§ 50.601-50.607 (2001), particularly §§ 50.603, 50.604(c)(1), 50.604(g) (2001). Identical regulations can be found at 45 C.F.R. §§ 94.2-94.6 (2002).

⁵⁶ For example, the startup's "Investigator Financial Disclosure Policy" sets forth similar requirements for NSF-funded researchers. 60 Fed. Reg. 35,820 (1995). Food and Drug Administration ("FDA") regulations require that when companies submit clinical trial data to the FDA for marketing approval of new drugs, they must list all clinical investigators who conducted the clinical trials. They must also disclose the financial interests of all academic (and other non-employee) clinical investigators in the outcome of the trials. 21 C.F.R. § 54 (2002).

⁵⁷ See ASS'N OF AM. UNIV., REPORT ON INDIVIDUAL AND INSTITUTIONAL FINANCIAL CONFLICTS OF INTEREST (2001) (outlining the Association's model guidelines), available at <http://www.aau.edu/research/COI.01.pdf>.

American Medical Colleges has issued model guidelines.⁵⁸ In what appears to be the most strict recommendation so far by a major academic association, the American Society of Gene Therapy recently required that "all investigators and team members directly responsible for patient selection, the informed consent process and/or clinical management in a [human] trial not have equity, stock options or comparable arrangements in companies sponsoring the trial."⁵⁹ Draft interim guidance issued by the PHS does not call for the exclusion of persons with such interests from participating in clinical trials. But it does call for Institutional Review Boards ("IRBs") to review any financial arrangements between universities and companies sponsoring clinical research sponsors, for conflict-of-interest committees to review relationships between sponsoring companies and individual clinical researchers, and for IRBs to consider informing prospective research subjects of such relationships.⁶⁰ However, policies still vary considerably from institution to institution.⁶¹ This is an area of active debate and changes in institutional policies.⁶²

Patients (or their next of kin) have filed suits alleging harm as a result of participating in clinical studies in which the academic researchers had financial interests in the outcome that were not dis-

⁵⁸ See ASS'N OF AM. MED. COLL., PROTECTING SUBJECTS, PRESERVING TRUST, PROMOTING PROGRESS—POLICY AND GUIDELINES FOR THE OVERSIGHT OF INDIVIDUAL FINANCIAL INTERESTS IN HUMAN SUBJECTS RESEARCH (2001) (outlining the Association's model guidelines), available at <http://www.aamc.org/members/coitf/firstreport.pdf>.

⁵⁹ AM. SOC'Y OF GENE THERAPY, POLICY OF THE AMERICAN SOCIETY OF GENE THERAPY ON FINANCIAL CONFLICT OF INTEREST IN CLINICAL RESEARCH (2000), available at <http://www.asgt.org/policy/index.html>.

⁶⁰ U.S. PUB. HEALTH SERV., DRAFT INTERIM GUIDANCE, FINANCIAL RELATIONSHIPS IN CLINICAL RESEARCH: ISSUES FOR INSTITUTIONS CLINICAL INVESTIGATORS AND IRBs TO CONSIDER WHEN DEALING WITH ISSUES OF FINANCIAL INTEREST AND HUMAN SUBJECT PROTECTION (2001), available at <http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/finguid.htm>.

⁶¹ See GEN. ACCOUNTING OFFICE (GAO), BIOMEDICAL RESEARCH: HHS DIRECTION NEEDED TO ADDRESS FINANCIAL CONFLICTS OF INTEREST, Report No. GAO-02-89 (2001) (examining that differing conflict-of-interest policies of five universities), available at <http://www.gao.gov/new.items/d0289.pdf>; Harrington, *supra* note 54.

⁶² Jocelyn Kaiser, *Proposed Rules Aim to Curb Financial Conflicts of Interest*, 295 SCI. 246, 246 (2002) (presenting the debate in the medical community following the implementation of new conflict-of-interest guidelines); Jerome P. Kassirer, *Financial Conflict of Interest: An Unresolved Ethical Frontier*, 27 AM. J. L. & MED. 149, 149-62 (2001); Kneller, *Technology Transfer*, *supra* note 7, at 766-68 (discussing NIH guidelines to increase access to "research tools" and restraints on publication).

closed to the patients.⁶³ However, there appear to be no cases to date where the alleged cause of action is based on a violation of the PHS or similar regulations.

2.2. U.S. Government Research Institutes

2.2.1. Sponsored Research Agreements

In 2000, GRIs, such as the NIH intermural laboratories, performed 19 billion USD of R&D as compared with 30 billion USD in universities.⁶⁴ In addition, 9 billion USD of federally funded R&D was performed in Federally Funded Research and Development Centers ("FFRDCs"). In some FFRDCs, discoveries are managed by the administering organization under the terms of the Bayh-Dole Law and Regulations. In others, the contract between the U.S. government and the administering organization calls for discoveries to be managed as if they arose in a GRI.⁶⁵ Since the 1960s, GRI researchers have been required to assign work-related inventions to the relevant government department,⁶⁶ but until the mid-1980s, these departments issued few licenses.⁶⁷ The 1986 Federal Technology Transfer Act⁶⁸ ("FTTA") gave individual GRIs authority to apply for patents and license inventions by their employees. In addition, the FTTA gave the laboratories authority to enter into sponsored research agreements with private companies, under which the companies could obtain IP rights to inventions arising under the sponsored research. The FTTA designates such agreements as "Cooperative Research and Development Agreements"

⁶³ Harrington, *supra* note 54, at 797.

⁶⁴ NAT'L SCI. BD., *supra* note 4, at A4-4.

⁶⁵ For example, discoveries made in the Department of Defense's Lincoln Laboratory (administered by MIT) and NASA's Jet Propulsion Laboratory (administered by California Institute of Technology ("Caltech")) are subject to Bayh-Dole and are managed by those respective universities' TLOs. However, technologies arising from DOE's Oak Ridge National Laboratory (administered by Lockheed Martin Corporation) and DOE's Los Alamos National Laboratory (administered by the University of California) are treated as if they arose in a GRI and are subject to the Federal Technology Transfer Act (see text immediately below). For a list of FFRDCs and their administering organizations, see <http://www.nsf.gov/sbe/srs/nsf02317/start.htm>.

⁶⁶ 37 C.F.R. § 501 (2002); 45 C.F.R. § 7.3 (2002).

⁶⁷ Kneller, *Technology Transfer*, *supra* note 7, at 769; See generally Eisenberg, *supra* note 13, at 1698-1705 (arguing that allowing universities to retain patent rights encourages commercial technology transfer).

⁶⁸ 15 U.S.C. § 3710a-d (2000).

("CRADAs"). At least in the case of NIH and other laboratories within the United States, PHS companies rarely, if ever, receive assignments of ownership in government inventions. Instead, the PHS Model CRADA grants CRADA collaborators "an exclusive option to elect an exclusive or nonexclusive commercialization license which is substantially in the form of the appropriate model PHS license agreement."⁶⁹

In this respect, corporate research sponsors obtain from GRIs rights to inventions similar to those from universities. However, additional restrictions apply to CRADAs that are not present in sponsored research agreements with universities. The FTTA requires that the government retain a nonexclusive, irrevocable, paid-up license to any CRADA inventions, including those made solely by employees of the CRADA partner.⁷⁰ CRADA opportunities must be advertised in the Federal Register prior to execution, unless the laboratory can demonstrate that only one company could be a suitable partner for the particular research project. In addition, individual laboratories may impose their own restrictions. The NIH is reluctant to use CRADA funds to pay part of the salaries of permanent professional employees, although CRADA funds are often used to hire postdoctoral-level researchers and technicians. Thus, CRADAs are not a source of soft-money salary support for tenured or tenure-track researchers—at least in NIH's intramural laboratories. Also, the CRADA partner has only 30 days (plus an additional 30 days upon written request) to review proposed publications of CRADA data in order to prepare patent applications and to make sure that confidential information is not divulged.⁷¹ There is no equivalent limitation in the Bayh-Dole Law or Regulations.

The FTTA only allows research sponsors to receive assignments or licenses to "inventions"—defined by the Bayh-Dole amendments and other technology-transfer laws as "any invention or discovery, which is or may be patentable or otherwise protected under this title."⁷² Copyright protection is not available for any work of the U.S. government—defined as a work prepared by an

⁶⁹ U.S. PUB. HEALTH SERV., MODEL COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT § 7.1 [hereinafter Model CRADA], available at <http://www.ott.od.nih.gov>.

⁷⁰ 15 U.S.C. § 3710a(b)(A) (2000).

⁷¹ Model CRADA, *supra* note 69, at § 8.7.

⁷² 35 U.S.C. § 201(d) (2000); 37 C.F.R. § 501.3(d) (2002).

officer or employee of the U.S. government as part of that person's official duties.⁷³ Therefore, companies collaborating with GRIs are not able to receive copyright to works produced under the research they support in GRIs, although they often can receive copyright to works produced in universities.

Unlike the Bayh-Dole Law and Regulations, the FTTA imposes explicit obligations on GRIs to give preference to U.S. business units when selecting CRADA partners. First, it obligates GRIs to "give special consideration to small businesses," which as noted above are defined as companies whose principal place of business is in the United States and which are mostly owned by U.S. citizens or permanent resident aliens.⁷⁴ Second, it obligates GRIs to give preference to business units located in the United States that agree that products embodying or made using CRADA inventions will be manufactured substantially in the United States. Before entering into a CRADA with a foreign-controlled organization, GRIs should also take into consideration whether that foreign country allows U.S. companies to enter into CRADA-like agreements with its GRIs.⁷⁵

2.2.2. *Licensing*

The above discussion concerning sponsored research agreements has already introduced the main points regarding licensing from GRIs. The 1986 FTTA⁷⁶ is important because it gives individual laboratories the right to manage IP and resulting royalties. However, the Bayh-Dole Law and Regulations⁷⁷ place important obligations on licenses by GRIs. Some of these obligations are similar to those they place on licenses of federally funded university inventions:

- 1) Exclusive licenses are subject to the irrevocable, royalty-free right of the U.S. government to practice or have practiced the invention on its behalf.⁷⁸
- 2) Preference should be given to small businesses in the granting of exclusive licenses.⁷⁹

⁷³ 17 U.S.C. §§ 101, 105 (2000).

⁷⁴ 15 U.S.C. § 3710a(c)(4)(A) (2000). *See also* discussion *supra* note 31.

⁷⁵ 15 U.S.C. § 3710a(c)(4)(B) (2000).

⁷⁶ *See* 15 U.S.C. § 3710a-d, *supra* note 69.

⁷⁷ 37 C.F.R. §§ 401, 404 (2002).

⁷⁸ *Id.* at § 404.7(a)(2), (b)(2).

⁷⁹ *Id.* at § 404.7(a)(1)(iv).

However, in the following respects, the Bayh-Dole Regulations place stricter requirements on the licensing of inventions from GRIs:

- 1) The applicant must submit a development or marketing plan when applying for either an exclusive or nonexclusive license.⁸⁰ The license must obligate the licensee to carry out this development plan and make the benefits of the invention reasonably accessible to the public.⁸¹ Also, the licensee must report periodically on its utilization of the invention.⁸²
- 2) An exclusive or *nonexclusive* license that grants the right to use the invention in the United States will normally be granted only if the licensee agrees that any products embodying the invention, or produced using the invention, will be manufactured substantially in the United States.⁸³ Taken together with the restrictions on entering into CRADAs with non-U.S. business units, discussed in the previous subsection, this amounts to more stringent restrictions on the transfer of GRI technologies to non-U.S. businesses or to businesses that will manufacture outside the United States, instead of applying transfer of university technologies. This issue is relevant to Japan's recent adoption of the "Japan manufacturing preferences" discussed in Section 3.4.
- 3) Sublicenses of either exclusive or nonexclusive licenses require approval of the federal agency.⁸⁴ In contrast, universities do not need to approve sublicenses.
- 4) Absent special justification, exclusive licenses can be granted only after publication of the licensing opportunity in the Federal Register.⁸⁵ Then, there must also be a Federal Register notice identifying the invention and the prospective exclusive licensee, followed by opportunity for written objections.⁸⁶ Finally, the federal agency must determine that an exclusive license is necessary to attract the private

⁸⁰ *Id.* at § 404.5(a)(1).

⁸¹ *Id.* at § 404.5(b)(5).

⁸² *Id.* at § 404.5(b)(6).

⁸³ *Id.* at § 404.5(2).

⁸⁴ *Id.* at § 404.5(b)(4). The regulations pertaining to universities let the universities themselves decide whether sublicenses require university approval.

⁸⁵ *Id.* at § 404.7(a)(1).

⁸⁶ *Id.* at § 404.7(a)(1)(i).

investment needed to develop the invention and that the public interest is best served by granting an exclusive license.⁸⁷

Details of the evolution of technology transfer from GRIs and summary statistics showing the extent of licensing from some of the major GRIs are in another publication available online.⁸⁸ Since 1994, the NIH and the other U.S. PHS laboratories have had a clearly articulated policy to issue exclusive licenses only if they are necessary to ensure sufficient incentives to develop PHS inventions—although inventions arising under CRADAs are exempt from this policy.⁸⁹

2.2.3. *Conflicts of Interest*

The FTTA requires agencies to establish standards of conduct to avoid conflicts of interest with respect to CRADAs. In addition, various federal laws set forth conflict-of-interest and ethics policies applicable to CRADAs. An analysis of these policies is beyond the scope of this paper, except to note the following: at least in the case of the NIH, key NIH scientists involved in a prospective CRADA must disclose their financial interests. Before the CRADA is approved, the designated ethics counselor of their institute(s) must certify either that a conflict of interest does not exist or that possible conflicts have been considered and appropriate waivers made. In general, stock holdings valued below \$5000 are considered waivable.⁹⁰ Outside activities drawing upon work-related skills, including outside employment, service on a board of directors, and consultation agreements, must be preapproved by ethics counselors.⁹¹ Generally, it is not permitted to be involved in a

⁸⁷ *Id.* at § 404.7(a)(1)(ii).

⁸⁸ Kneller, *Technology Transfer*, *supra* note 7, at 769-70.

⁸⁹ Memorandum from the Director of the Office of Technology Transfer, Public Health Service ("PHS"), NIH, to various directors at NIH, PHS, and the Office of Technology Transfer (referencing Amended Information and Information Memorandum No. OTT-94-305, "Procedures for Making Determinations Regarding the Grant of Exclusive or Partially Exclusive Licenses") (Aug. 10, 1995) (on file with author).

⁹⁰ See NAT'L INST. HEALTH, NIH POLICY MANUAL 2300-735-1, AVOIDING CONFLICTS OF INTEREST 10 (1998) (noting only financial interests in excess of \$5,000 create a conflict of interest), available at <http://ethics.od.nih.gov>.

⁹¹ See NAT'L INST. HEALTH, NIH POLICY MANUAL 2300-735-4, OUTSIDE WORK AND RELATED ACTIVITIES WITH OUTSIDE ORGANIZATIONS 6-13 (1998) (discussing permissibility of, and protocol, concerning NIH employees' activities with outside organizations), available at <http://ethics.od.nih.gov>.

CRADA with a company in which one is engaged in such outside activities.⁹² Thus, conflict-of-interest rules governing researchers who have financial interests in companies sponsoring collaborative research are generally stricter in the case of GRIs than universities.

2.3. Salient Features of the U.S. System

In summary, under the U.S. system, the research institutions themselves have ownership rights and they themselves manage technology development. Regulations are targeted to ensure:

- complete reporting;
- residual government rights in government-funded inventions;
- that inventors share in royalties;
- a preference for licensing to small businesses;
- a U.S. manufacturing preference for government-funded inventions; and
- in the case of GRI inventions, fair access to government-funded discoveries.

The scope of sponsored research and licensing involving private companies is substantial. The most controversial issues today concern issues of:

- conflicts of interest and conflicts of commitment;
- the preservation of academic freedom and scientific objectivity;
- protection of human research subjects;
- the appropriate balance between commercial and curiosity-motivated research;
- the appropriate balance between exclusive and nonexclusive licenses;
- the appropriate balance between licenses to faculty startup companies and licenses to established companies; and
- the concern that multiple and sometimes overlapping IP rights, particularly in early-stage inventions, might hinder technology development.

⁹² See NAT'L INST. HEALTH, NIH POLICY MANUAL 2300-735-1, *supra* note 90, at 10 (delineating conflict-of-interest rules).

3. THE JAPANESE SYSTEM

3.1. *Japanese Universities*

3.1.1. *Background*

Japanese national universities, which account for at least 75% of university R&D and include Japan's most prestigious universities,⁹³ have no independent administrative or financial status. They are branches of the Ministry of Education, Culture, Sports, Science and Technology ("MEXT"), and thus their laboratories are Japanese government laboratories. With a few exceptions, all of their faculty and administrators are civil servants. Faculty salaries are fixed nationwide based primarily on number of years in service. Advanced degrees and number and quality of publications have only a small effect on salaries. Soft-money supplementation of the salaries of civil servants, including all full-time academic researchers in national universities, is forbidden. Until recently, opportunities to use soft money to pay salaries or stipends for secretaries, technicians, graduate students, and postdoctoral researchers were severely limited, and restrictions still exist, as described below. The administrative staffs of national universities are career MEXT bureaucrats who usually spend two years in one administrative office and then rotate to another, sometimes in a different university. Often they do not develop in-depth knowledge of, or loyalty towards, the particular research center in which they happen to be stationed. Therefore, in terms of administration, finance, and personnel, Japanese national universities are significantly different from U.S. universities.

Constraints on technology transfer from nonuniversity GRIs have traditionally been even greater. However, significant reforms have recently occurred in the GRIs that have become "independent administrative entities."⁹⁴ Many of these quasi independent GRIs have leapfrogged national universities in terms of openness to cooperation with industry.

The national universities themselves are scheduled to become

⁹³ See Kneller, *Intellectual Property Rights*, *supra* note 2 ("[M]ost highly regarded universities are National Universities. . . . Most of the National Universities have graduate schools, and they account for approximately 75% of total R&D expenditures.").

⁹⁴ Japanese: *doku-ritsu gyō-sei hō-jin*.

independent administrative entities in 2004. Section 3.1.7 will discuss these university reforms.

A few private universities are highly regarded researcher centers. Subsection 3.1.6 will summarize technology transfers from such institutions.

3.1.2. *Sponsored Research Agreements with Industry*

It has been difficult for corporations to support research in Japanese universities in a manner that creates incentives for effective technology development. The main legal/administrative problems involve:

- limitations on the IP rights sponsors can obtain;
- barriers to the smooth disbursement of corporate research support; and
- restrictions on the use of such funds to employ and motivate people.

Thus, the technology-transfer issues that confront Japan in part reflect IP issues that were current in the United States in pre-Bayh-Dole, pre-FTTA era. But they also reflect legal and institutional barriers to university-industry cooperation that have not existed for decades in the United States.

This Subsection discusses these problems, some of the measures that have been devised to cope with them, recent reforms, and some of the social and institutional factors that affect the effectiveness sponsored research. It first analyzes formal contractual agreements, i.e., Commissioned or Joint Research Contracts. Next, it discusses "Donations," which in theory are charitable gifts but are, in fact, a widely used informal mechanism for companies to sponsor research in universities.

3.1.2.1. *Commissioned and Joint Research Contracts*

If a company intends to support research in a national university based upon a written research protocol, or if it wants contractually based rights to data or intellectual property, then it must enter into either a "Commissioned" or "Joint Research" contract with the university administration.⁹⁵ The principal

⁹⁵ These are specific types of contracts embodying specific administrative restrictions and obligations. The transliterated Japanese term for Commissioned Research is *jutaku kenkyuu* and for Joint Research is *kyoudou kenkyuu*, which is an abbreviation of the formal term, "Joint Research with Private Sector Entities and the Like." Japanese: *minkan nado to no kyoudou kenkyuu*.

difference between these two types of agreements is that company researchers can work in university laboratories under Joint Research Contracts, but not under Commissioned Research Contracts.

3.1.2.1.1. *IP and Data Rights*

3.1.2.1.1.1. *Overview*

The guidelines governing Commissioned or Joint Research Contracts are set forth in "guidance notifications" ("Notifications") issued by the MEXT or its predecessor, the Ministry of Education, Science, Sports and Culture ("Monbusho," the official Japanese name).⁹⁶ Notifications are neither laws nor regulations, but rather administrative guidance indicating what government ministries consider to be permissible behavior.⁹⁷ The principal Notifications

⁹⁶ In 2001, Monbusho and the Science and Technology Agency ("STA") merged to form MEXT. Monbusho was responsible for most aspects of education from kindergarten to advanced graduate level research institutes. Traditionally, Monbusho left considerable authority in the hands of professors and their universities. It was known as a relatively "bottom-up" ministry, at least as far as control over university affairs was concerned. STA managed big budget national space and nuclear energy programs as well as other R&D programs in areas such as deep sea exploration, genomics, and brain research. STA laboratories had their own research staffs, which with a few exceptions, were not closely involved in graduate-level training. STA had the reputation of having a "top-down" style of administration. As described below, it also tried to position itself as a technology management agency for other national and local government R&D organizations. The integration within MEXT of the contrasting cultures and missions of Monbusho and STA is still incomplete.

⁹⁷ Since 1992, many of the Notifications related to university-industry cooperation have been compiled in a book, DAIGAKU TO SANGYOUKAI TO NO KENKYUU KYOURYOKU JIMU HIKKEI, DAINIJI KAITEIBAN [ADMINISTRATIVE HANDBOOK FOR RESEARCH COOPERATION BETWEEN UNIVERSITIES AND INDUSTRY] (1992) (in Japanese, published by a semi-official publishing house, "Gyousei") [hereinafter HANDBOOK FOR RESEARCH COOPERATION 1992]. The Fourth Edition, published in 2002, contains substantially more information than the Third Edition published just two years earlier, which in turns contains substantially more information than the Second Edition published in 1997. These compilations, as well as postings on the Internet under the home pages of major government ministries, make many (but not all) of the important Notifications accessible to those who know where to look.

Nevertheless, the Notifications have taken on a life of their own and assumed authority at least as great as that of regulations under U.S. law. This authority is due largely to the practice of government officials at all levels rotating to different positions approximately every two years. New transferees into positions related to university-industry cooperation often have no previous experience in this area. The Notifications provide their main guidance, just as they do for the persons above and below them in the administrative hierarchy. Thus, bureaucrats at all

governing Commissioned or Joint Research Contracts are:

- Notification No. 260 of 1970,⁹⁸ which established the administrative rules and some of the IP ground rules for Commissioned Research Contracts;
- Notification No. 117 of 1978,⁹⁹ which set forth two tests to determine when a national university invention should belong to the nation rather than to the faculty-inventor. However, the applicability of this notification to company-funded Commissioned or Joint Research inventions was not clear until the issuance of Notification No. 163 of 1999;

administrative levels have strong incentives to comply with the Notifications. During their tenures in a particular position, few bureaucrats develop enough knowledge, conviction, and authority to make changes. The bureaucrats are indeed caught in their own web, able neither to understand all of the effects of the Notifications nor to change them.

Changes are usually initiated from the outside—not by persons responsible for university-industry cooperation, but rather by senior ad hoc advisory committees, reform minded officials in other ministries with powerful political backing, and new laws requiring a revision of existing Notifications. However, few outside government officials, university researchers, companies, or members of the public or their elected representatives, grasp the complete web of rules created by the various Notifications. Thus the complexity of the Notifications and the impersonal way they are administered greatly reduces the obvious targets for change for reform-minded outsiders. In other words, change is possible, but not easy. Furthermore, implementing reforms (i.e., rationalizing the Notifications and reducing the bureaucratic inertia that undergirds existing practices) is even more difficult. See, e.g., *infra* note 135.

⁹⁸ Jutaku Kenkyuu no Tori-atsukai ni tsuite: Kaikei Kachou, Daigaku Gakujutsu Kyokuchou Tsuuchi Mon-kai-sou Nado 260 gou [Handling of Commissioned Research: Monbusho Accounting-General Affairs Notification No. 260] (Apr. 30, 1970) (amended by Notification Nos. 115 of 1988 and 184 of 1997), in DAIGAKU TO SANGYOUKAI TO NO KENKYUU KYOURYOKU JIMU HIKKEI, DAINIJI KAITEIBAN [ADMINISTRATIVE HANDBOOK FOR RESEARCH COOPERATION BETWEEN UNIVERSITIES AND INDUSTRY] (2d ed. 1997) (in Japanese, published by Gyousei) [hereinafter HANDBOOK FOR RESEARCH COOPERATION 1997].

⁹⁹ Kokuritsu Daigaku nado no Kyoukan nado no Hatsumei ni kakawaru Tokkyo nado no Tori-atsukai in Tsuite: Gakujutsu Kokusai Kyokuchou, Kaikei Kachou Tsuuchi Mon-gaku-jutsu nado 117 gou [Handling of Patents Relating to Inventions of National University Faculty: Monbusho Science Notification No. 117] (Mar. 25, 1978) (amended by Notifications No. 138 of 1987, No. 163 of 1997, and No. 163 of 1999), in DAIGAKU TO SANGYOUKAI TO NO KENKYUU KYOURYOKU JIMU HIKKEI, DAINIJI KAITEIBAN [ADMINISTRATIVE HANDBOOK FOR RESEARCH COOPERATION BETWEEN UNIVERSITIES AND INDUSTRY] (4th ed. 2002) (in Japanese, published by Gyousei) [hereinafter HANDBOOK FOR RESEARCH COOPERATION 2002], available at http://www.mext.go.jp/a_menu/shinkou/sangaku/index.htm.

For a version prior to the amendment by Notification No. 163 of 1999, see HANDBOOK FOR RESEARCH COOPERATION 1997, *supra* note 98.

- Notification No. 195 of 1983,¹⁰⁰ which established the administrative structure and some of the IP rules governing Joint Research Contracts;
- Notification No. 172 of 1984,¹⁰¹ which established procedures for licensing inventions arising under Commissioned or Joint Research Contracts;
- Notification No. 163 of 1999,¹⁰² which modifies No. 117 of 1978¹⁰³ and specifically addresses Commissioned or Joint Research inventions;
- Notification No. 230 of 2000,¹⁰⁴ which permits transfer of ownership of Joint Research inventions to the sponsoring companies, provided they pay "appropriate compensation" to the national treasury and the transfer is expected to result in development of the invention; and,
- Notification No. 292 of 2001,¹⁰⁵ the latest in a series of Notifications revising and replacing No. 260 of 1970 pertaining to Commissioned Research Contracts.

In addition, two laws, which on their face have little connection

¹⁰⁰ Minkan nado to no Kyoukou Kenkyuu no Toriatsukai ni tsuite: Gakujutsu Kokusai Kyokuchou, Kaikei Kachou Tsuuchi Mon-gaku-jo nado 195 gou [Handling Joint Research: Monbusho Science Notification No. 195] (May 11, 1983) (amended by Notifications No. 172 of 1984 and No. 186 of 1997), in *HANDBOOK FOR RESEARCH COOPERATION 2002*, *supra* note 99, at 278-82, available at http://www.mext.go.jp/a_menu/shinkou/sangaku/index.htm.

¹⁰¹ Jutaku Kenkyuu oyobi Minkan nado to no Kyoudou Kenkyuu ni kakawaru Tokkyo nado no Jisshi nado ni tsuite: Gakujutsu Kokusai Kyokuchou, Kaikei Kachou Tsuuchi Mon-gaku-jo nado 172 gou [Licensing of Patents Related to Commissioned Research and Joint Research: Monbusho Science Notification No. 172] (May 8, 1984) (amended by Notification No. 186 of 1997), in *HANDBOOK FOR RESEARCH COOPERATION 2002*, *supra* note 99, at 434-35, available at http://www.mext.go.jp/a_menu/shinkou/sangaku/index.htm.

¹⁰² "Kokuritsu Daigaku nado no Kyoukan nado no Hatsumei ni kakawaru Tokkyo nado no Tori-atsukai in Tsuite" no ichibu Kaisei ni tsuite (tsuuchi): Mon-gaku-jo nado 163 gou [Notification Partially Revising Handling of Patents Relating to Inventions of National University Faculty: Monbusho Science Notification No. 163] (Mar. 24, 1999) (in Japanese) (copy on file with author).

¹⁰³ *HANDBOOK FOR RESEARCH COOPERATION 2002*, *supra* note 99.

¹⁰⁴ Kokuritsu Daigaku nado ni o tsukeru tokkyo nado no soshiki-teki na kanri, katsuyou no suishin ni tsuite (tsuuchi): Mon-gaku-jo nado 230 gou [Promoting the organizational management and usefulness of patents from national universities: Monbusho Science Notification No. 230] (Dec. 27, 2000) (in Japanese) (copy on file with author).

¹⁰⁵ Jutaku Kenkyuu no Tori-atsukai ni tsuite: Kenkyuu Shinkou Kyokuchou, Kaikei Kachou Tsuuchi 12 Mon-ka-shin nado 292 gou [Handling of Commissioned Research: MEXT Science Notification No. 292] (Mar. 30, 2001) in *HANDBOOK FOR RESEARCH COOPERATION 2002*, *supra* note 99, at 331-46.

with sponsored research in universities, also have important implications for Commissioned or Joint Research contracts:

- 1) The Finance Law¹⁰⁶ § 14 states: "All revenue and income must be included in the national budget."
- 2) The General Accounts Law¹⁰⁷ § 2 states: "The director of each ministry or agency should pay income under his jurisdiction into the national treasury. The money cannot be used directly."

MEXT and the Ministry of Finance ("MOF") have interpreted these two laws to mean that even if research funds come from private companies, because the research takes place in national universities where it is used for public service, these funds cannot be regarded as private funds. Rather they must be included in the appropriate (national) budget income and expenditure accounts.¹⁰⁸

Coupled with the above provisions of the Finance and General Accounts Laws, the above mentioned Notifications have the following principal effects:

- 1) Commissioned or Joint Research contracts can be negotiated directly between national universities and corporate sponsors.¹⁰⁹ However, the basic terms of these contracts are set by MEXT.¹¹⁰
- 2) Funds must be disbursed through the MOF which deducts 30 percent as "overhead" to augment the national higher education budget. No overhead payments are distributed directly to the university or the inventor.¹¹¹
- 3) Inventors probably should report all potentially commercially valuable Commissioned or Joint Research

¹⁰⁶ Zaisei Hou [Financial Law], Law No. 34 of 1947, available at http://www.houko.com/00/FS_SE.HTM (last visited May 7, 2003).

¹⁰⁷ Kaikei Hou [General Accounts Law], Law No. 35 of 1947, available at <http://www.houko.com> (last visited May 7, 2003).

¹⁰⁸ HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99, at 2.

¹⁰⁹ Notification No. 260 of 1970, in HANDBOOK FOR RESEARCH COOPERATION 1997, *supra* note 98; Notification No. 195 of 1983, in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99; Notification No. 292 of 2001, in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99.

¹¹⁰ Kyoudou Kenkyuu Keiyaku Sho [Joint Research Contract] in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99, at 119-43; Jutaku Kenkyuu Keiyaku Sho [Commissioned Research Contract] in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99, at 164-74.

¹¹¹ Written communication from University of Tokyo (Mar. 19, 2002) (on file with author). HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99, at 34-35.

inventions to their university's "Invention Committee."¹¹²

- 4) Any patentable or commercially useful inventions should be owned or co-owned by the university as the representative of the nation.¹¹³ The complex basis for this far-reaching conclusion is discussed in the next subsection.
- 5) However, corporate sponsors of Commissioned Research can prenegotiate the right to receive a portion of the university's ownership right to any resulting patentable inventions.¹¹⁴ The prenegotiated terms may also allow the company, once it receives assignment of a portion of the university's right, to pay the majority of patent prosecution costs and to control the patent application process. Alternatively, the company can request from the university president a 10-year renewable preferential license,¹¹⁵ which is essentially an exclusive license with development and royalty payment obligations and government "march in" rights (i.e., compulsory licensing rights in emergency situations).¹¹⁶ Not surprisingly, most companies opt to negotiate for co-ownership.¹¹⁷
- 6) Corporate sponsors of Joint Research can also prenegotiate similar co-ownership rights. If one of the sponsor's employees is a co-inventor, co-ownership is automatic, and the sponsor and university can jointly decide upon the patent application strategy and allocation of ownership rights.¹¹⁸

¹¹² Compare Notification No. 195 of 1983, in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99, at § 5(6)1, (requiring the reporting of inventions made under Joint Research Contracts), with Notification No. 260 of 1970, in HANDBOOK FOR RESEARCH COOPERATION 1997, *supra* note 98; Notification No. 292 of 2001, in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99; and Notification No. 172 of 1984, in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99 (embodying a strong collective presumption towards the reporting of Commissioned Research inventions).

¹¹³ Notification No. 163 of 1999, *supra* note 102.

¹¹⁴ Notification No. 292 of 2001 in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99, at 331-46.

¹¹⁵ Japanese: *yu-u-sen jisshi ken*.

¹¹⁶ Notification No. 172 of 1984 in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99, at 434-35.

¹¹⁷ Records of the University of Tokyo's Invention Committee indicate that since at least 1997, the University has not received any royalties for preferential licenses (on file with author). Oral communications in 2002 with the Committee secretariat indicate that probably no such licenses have been issued.

¹¹⁸ When all inventors are university personnel, the sponsor has no explicit

- 7) In the case of commercial sales, the company is obligated to pay royalties to the national treasury, although none of these royalties will flow directly to the university or the inventor.¹¹⁹
- 8) Under Article 73(1)(3) of Japan's Patent Law,¹²⁰ the approval of all co-owners is necessary for any licenses or assignments to third parties. A nonexclusive license¹²¹ needs only the prior approval of the university's property management office,¹²² with later notification to MEXT. A preferential license requires approval of the university president.¹²³ However, full exclusive licenses¹²⁴ must be approved in advanced by the MEXT Minister.¹²⁵ Discussions with university scientists, company officials, and managers of venture capital funds indicate that the restrictions and

right to obtain co-ownership. For more detailed information, see Joint Research Contract, in *HANDBOOK FOR RESEARCH COOPERATION 2002*, *supra* note 110; Notification No. 260 of 1970, in *HANDBOOK FOR RESEARCH COOPERATION 1997*, *supra* note 98; and Notification No. 292 of 2001, in *HANDBOOK FOR RESEARCH COOPERATION 2002*, *supra* note 105. Nevertheless, University of Tokyo Invention Committee records and conversations with company representatives suggest that sponsors of Joint Research almost always obtain the right to jointly apply for patents. Also, companies say that they prefer the IP rights provisions of Joint Research as opposed to Commissioned Research contracts. The Author is not sure whether most of the jointly-filed Joint Research patent applications list both university and sponsor inventors, or whether listed sponsor inventors actually merit designation as inventors.

¹¹⁹ Notification No. 260 of 1970, in *HANDBOOK FOR RESEARCH COOPERATION 1997*, *supra* note 98; Notification No. 195 of 1983, in *HANDBOOK FOR RESEARCH COOPERATION 2002*, *supra* note 100; Notification No. 172 of 1984, in *HANDBOOK FOR RESEARCH COOPERATION 2002*, *supra* note 101; and, Notification No. 292 of 2001, in *HANDBOOK FOR RESEARCH COOPERATION 2002*, *supra* note 105.

¹²⁰ Tokkyo Hou [Patent Law], Law No. 121 of 1959, § 121, *available in English* at <http://www.jpo.go.jp>.

¹²¹ Japanese: *tsuu-jou jissshi ken*.

¹²² Japanese: *jimukyoku kanzaiika*. Written communication from University of Tokyo, Office of Cooperative Research, to the Author (Jan. 21, 2002) (on file with author).

¹²³ See *infra* note 139.

¹²⁴ Japanese: *doku-sen tsuu-jou jissshi ken*, which allows the licensor to retain a use right, or *sen-you jissshi ken*, under which the licensor yields even use rights and which must be registered in the Japanese Patent Office. Patent Law, *supra* note 120, at § 98.

¹²⁵ Written communication from MEXT (Feb. 12, 2002). The more stringent approval requirements associated with higher degrees of exclusivity derive from the National Properties Law (§§ 2, 3, 21) and the Finance Law (§ 9) which require approval and appropriate compensation for any alienation of national property. See *infra* note 128; Financial Law, *supra* note 106.

uncertainty regarding third-party transfers is the most problematic aspect of Commissioned or Joint Research from an IP perspective. Restrictions on the transferability of exclusive IP rights are particularly onerous for startup companies.

- 9) Under Article 73(2) of Japan's Patent Law,¹²⁶ each co-owner of a patent has the right to exploit the invention without the consent of the other co-owners unless otherwise prescribed by contract. Although the Author knows of no case of a Japanese university competing with one of its patent co-owners, the possibility of such competition is of concern to some companies contemplating Commissioned or Joint Research with universities as well as venture funds considering investing in such companies.¹²⁷

3.1.2.1.1.2. *Details of ownership and invention reporting*

This Section provides details on ownership of inventions made in Japanese universities. Despite the centrality of ownership to technology transfer, ownership remains the most complicated and ambiguous aspect of Commissioned or Joint Research. Readers who are short of time or who wish to accept the above summary of ownership at face value may skip this Section, perhaps returning to it while reading Section 3.1.3 on licensing.

Prior to 1978, there was a presumption based upon the National Properties Law¹²⁸ that all inventions made in national universities belonged to the nation. Furthermore, such inventions should be patented and licensed nonexclusively by central government bureaus—with the limited exception noted under (5) above, enabling sponsors of Commissioned Research to co-own inventions.¹²⁹ However, as corporate interest in university discover-

¹²⁶ Patent Law, *supra* note 120, at § 73(2).

¹²⁷ There is no precedent for a university signing a noncompetition contract with a company sponsoring Commissioned or Joint Research. Any such contract would require time-consuming approval from senior MEXT officials. However, under Notification No. 172 of 1984, the president of a national university probably could grant a preferential license of the university's rights to the sponsor, under which the university president could probably commit his university to not commercially exploit the invention. Notification No. 172 of 1982, in *HANDBOOK FOR RESEARCH COOPERATION 2002*, *supra* note 101.

¹²⁸ Kokuyuu Zaisan Hou [National Properties Law], Law No. 73 of 1948, available at <http://www.houko.com/00/01/S23/073.htm>.

¹²⁹ Notification No. 260 of 1970, in *HANDBOOK FOR RESEARCH COOPERATION 1997*, *supra* note 98.

ies grew during the 1970s, pressure mounted, as it also did in the United States, to lower barriers to university-industry cooperation. Japanese academics had always retained copyright over copyrightable materials. Some officials in Monbusho reasoned by analogy that national university faculty members should retain IP rights to their patentable discoveries. Discussions with the MOF resulted in a compromise under which an invention that met either of the following criteria would be designated as a "National Invention," the ownership of which would automatically belong to the nation:¹³⁰

- 1) the invention arose as a result of research performed using special funding from the nation for projects aimed at the development of practical applications; or
- 2) the invention arose as a result of research performed utilizing special research facilities (such as nuclear power research facilities and particle accelerators) established for use in government-sponsored research and under a specific research project aimed at developing practical applications.

If neither criteria applied, the faculty inventor could maintain ownership. This compromise was embodied in Monbusho Notification No. 117 of 1978.¹³¹

A literal reading of Notification No. 117 might imply that Commissioned or Joint Research Projects *funded only by private companies* would not meet either of the criteria for classification as a National Invention and therefore would not have to be reported. However, as noted above, MEXT and the MOF have interpreted the Finance and General Account Laws¹³² to mean that project-specific private sector funds must be included in the appropriate national budget income and expenditure accounts. It follows that these funds have to be dispersed first from the company to the MOF, which then disperses the funds to MEXT, which then disperses the funds to the universities.

Notification No. 163 of 1999¹³³ amended Notification No. 117 of 1978 to explicitly address ownership of Commissioned or Joint Research inventions. The two criteria for classifying an invention as

¹³⁰ See *infra* note 142 (regarding whether transfer of ownership to the nation is self executing).

¹³¹ Notification No. 117 of 1978, in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99.

¹³² See Financial Law, *supra* note 106. See also General Accounts Law, *supra* note 107.

¹³³ Notification No. 163 of 1999, *supra* note 102.

belonging to the nation now read as follows:

- 1) The invention arose as a result of research performed using special research funds provided by the nation for a specific research project aimed at developing practical applications—including Joint Research funds, Commissioned Research funds, and MEXT Grants-in-Aid, but excluding general research expenses such as faculty research allowances and Donations.
- 2) The invention arose as a result of research performed using special large-scale facilities established specially by the nation, such as atomic reactors, nuclear fusion facilities and atomic particle accelerators (but excluding general purpose equipment such as computers); and under a specific research project aimed at developing practical applications.

The main change is the explicit classification of Commissioned or Joint Research, as well as Grant-in-Aid, inventions as “National Inventions,” provided they arise under project-specific funds that envisaged practical applications of the research results.¹³⁴

Notification No. 117 of 1978 and No. 163 of 1999 also obligate each national university to establish an “invention committee,” as well as procedures under which faculty members report inventions to their university president. The president, acting upon the advice of the invention committee, will decide whether the reported inventions should be designated as “National Inventions” on the basis of the above two criteria.¹³⁵ In order to implement Notification

¹³⁴ In addition, some Notifications convey a strong presumption that all Commissioned or Joint Research inventions should be classified as National Inventions, although the government can transfer a portion of its rights to private sponsors. See Notification No. 260 of 1970, in *HANDBOOK FOR RESEARCH COOPERATION* 1997, *supra* note 98, at § 2(2); Notification No. 292 of 2001, in *HANDBOOK FOR RESEARCH COOPERATION* 2002, *supra* note 105, at § 2(2); Notification No. 195 of 1983, in *HANDBOOK FOR RESEARCH COOPERATION* 2002, *supra* note 100, at § 5(6)4; Notification No. 172 of 1984, in *HANDBOOK FOR RESEARCH COOPERATION* 2002, *supra* note 101.

¹³⁵ University administrators also play a significant behind the scenes role in the work of the Invention Committees. Committee meetings are usually held once or twice a year and deal with policy issues and a review of statistical data. There is hardly ever discussion about specific inventions. Instead, reports of inventions have already been dealt with at the department or center level. Usually department level administrative personnel ask the inventor to fill out a short questionnaire that asks *in general terms* about sources of funding, whether the funding was project-specific and whether the invention is patentable. The inventor's answers determine whether she can retain ownership. Answers are hardly ever questioned. The process is pro forma. The administrative staff responsible for processing the inventor's answers are usually not familiar with the intricacies

No. 117 of 1978, some universities, such as the Tokyo Institute of Technology and Tohoku University, enacted strict internal rules that require reporting of all inventions made with project-specific government funds, as well as all inventions arising under Commissioned or Joint Research Contracts.¹³⁶ However, the University of Tokyo's internal regulations *permit faculty members to judge whether their inventions fall under one of the criteria for classification as a National Invention*. If a University of Tokyo inventor feels confident that these criteria do not apply to his invention, he is not required to report.¹³⁷ Several other national universities follow the University of Tokyo's lead with respect to invention reporting.

Thus, on balance, it becomes clear that national universities, acting on behalf of the nation, should have an ownership interest in all Commissioned or Joint Research inventions, even those funded entirely by private sector corporations. However, as the above discussion indicates, this conclusion is not always obvious to university researchers, corporate collaborators, private investment funds, or even university administrators. Although most realize that the government maintains at least partial ownership, the Author has found uncertainty and occasionally fundamental misunderstanding concerning ownership among some university administrators and corporate executives. Even senior university and government officials responsible for university-industry cooperation have difficulty explaining the basis for the government's ownership interest. In summary, the laws and Notifications that establish the government's ownership interest:

- lack clarity and are administered in a pro forma manner by rank-and-file university administrators (if unusual situa-

of invention ownership. They simply follow set procedures to comply with applicable Notifications. This is another example of how the complex web of administrative guidance Notifications turns the technology transfer process into a pro forma bureaucratic exercise that ensures surface-level compliance with rigid rules, and thereby forecloses meaningful debate by persons with ostensible responsibility to oversee and improve the process. See HANDBOOK FOR RESEARCH COOPERATION 1992, *supra* note 97.

¹³⁶ Toukyou Kougyou Daigaku Hatsumeiki Kisoku [Tokyo Institute of Technology Invention Rules] (1978) (on file with author); Touhoku Daigaku Kyoukan nado Hatsumeiki Tori-atsukai Kitei [Tohoku University Rules for Handling Faculty Inventions (1978)] (on file with author).

¹³⁷ Toukyou Daigaku Hatsumeiki Kisoku [University of Tokyo Invention Rules] Nos. 3-5 (1979) (amended 1993); Toukyou Daigaku Hatsumeiki Kisoku Saishoku [Regulations Implementing the University of Tokyo Invention Rules] (1984) (amended 1989) (on file with author).

tions arise, higher-level bureaucrats are hesitant to make precedent-setting decisions);

- fail to provide incentives for any university or MEXT office to monitor Commissioned or Joint Research inventions; and
- create an uneven or weak obligation to report inventions, leading to the absence of data to assess the effectiveness of technology transfer.

The implications of these shortcomings are addressed below.

3.1.2.1.1.3. *Third-party transfers: Additional considerations*

A corporate sponsor that co-owns a Commissioned or Joint Research invention need only obtain approval from the president of the co-owning university in order to issue a preferential license to another company.¹³⁸ A preferential license is similar to a typical exclusive license from a U.S. university or a sublicense.¹³⁹ In theory, obtaining approval from a university president need not be difficult or time-consuming. Nevertheless, this Author knows of only two cases of royalty-earning transfers of rights to Commissioned or Joint Research inventions. One involved a license of a Joint Research invention from a major national university to an affiliate of the sponsor, a regional gas company.

The other involved a Joint Research invention co-owned by the sponsoring company (Company A) and a major national university that company A wanted to transfer to another company (Company B). The mechanism to affect this transfer was not a preferential license. Rather, the university's TLO requested assignment of the university's/nation's ownership interest under Notification No. 230 of 2000.¹⁴⁰ Then the TLO planned to assign or exclusively license this interest to Company B. Negotiating the transfer from the university to its TLO took two years. Frequent consultations between university administrators and central MEXT bureaucrats

¹³⁸ Written communication from MEXT to Author (Apr. 2002). This message cited Notification No. 172 of 1984 as authority, even though this Notification speaks only about the authority of a national university president to issue a preferential license for the university's/nation's interest. Notification No. 172 of 184, in *HANDBOOK FOR RESEARCH COOPERATION 2002*, *supra* note 101. Evidently, this authority is now recognized within MEXT as the basis for authorizing the university president to approve a preferential license of the sponsor's interest to a third party.

¹³⁹ See *infra* § 2.1.2.

¹⁴⁰ Notification No. 230 of 2000, *supra* note 104.

probably occurred. The transfer was finally approved in June 2002. The "fair value" of the nation's/university's interest was ultimately assessed at less than \$400, which the TLO paid to the MOF's national university account. During the negotiations, the fact that a licensee, company B, had been identified had to be officially disguised.

This example shows the arduous process entailed in transferring the nation's co-ownership interest in company-sponsored Commissioned or Joint Research inventions. Despite the facts that (a) Notification No. 230 of 2000 allows the sponsoring company to receive the government's ownership share if it pays appropriate consideration, (b) the value of the nation's interest was ultimately decided to be trivial, and (c) Notification No. 230 does not require approval by central MEXT Authorities, the process took numerous person-hours and indeed involved central MEXT officials. This case provides a clue as to why there are few transfers to third parties of the nation's co-ownership rights. Even an application for a preferential license would meet unexpected delays as university administrators at the department level and the president's office debated the request and consulted with central MEXT bureaucrats. The next subsection examines another likely reason: the ability to avoid the designation of "Commissioned" or "Joint Research" invention.

3.1.2.1.1.4. *Practical implications*

Even though clear understanding of technology transfer laws and Notifications is rare, there is a pervasive impression that classification as a Commissioned or Joint Research invention means commercialization will be difficult. Therefore, there is a widespread incentive to avoid this classification. The following are some of the methods commonly employed:

- 1) The research scope of Commissioned or Joint Research projects is defined narrowly, so as to increase the likelihood that inventions that do occur are arguably outside the intended scope of the project. If an invention arises, it is often attributed to other sources of R&D support, usually Donations or "Kouhi," because Notification No. 117 of 1978 and No. 163 of 1999¹⁴¹ permit inventors to retain ownership

¹⁴¹ Notification No. 117 of 1978 in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99; Notification No. 163 of 1999, *supra* note 102.

over discoveries arising under such support. Then the inventors will directly transfer the inventions to the sponsors, often without a contract, as described below in Section 3.1.3.

- 2) University researchers involved in Commissioned or Joint Research projects with private companies deliberately do not report discoveries to university invention committees, nor apply for patents themselves. Sometimes they avoid carrying out experiments that would constitute reduction to practice. Instead, they make their research data available to the sponsoring company so that the company can pursue parallel research and file patent applications. Usually the company includes the key university researchers among the inventors named on its patent applications.

No one voiced concern that later someone may trace the university inventors' source of funding to a Commissioned or Joint Research project, and then assert that the Nation should have an ownership interest in the patent or that the purported owner does not have standing to sue an alleged infringer. However, it may be unwise to ignore this risk, if the defendant in a future infringement suit seeks to undermine the plaintiff's rights to a valuable invention that actually arose under Commissioned or Joint Research.¹⁴²

¹⁴² As under U.S. patent law, the right to apply for a Japanese patent originally rests with the inventors. Patent Law, *supra* note 120, at § 29. However, Monbusho Notification Nos. 117/163 of 1978/1999 states in § 1(1) that "in principle, a national university invention becomes the property of the nation in the event that either of the conditions listed this Notification applies" may effect a *self-executing transfer* of the inventors' rights to the nation. Notification No. 117 of 1978 in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 99; Notification No. 163 of 1999, *supra* note 102. In other words, even if the inventions were not reported to the appropriate invention committee, it may automatically be a national invention if it meets one of the criteria in Notification Nos. 117/163. Conceivably this may even be the case if the inventions were reported, but the invention committee erroneously decided that the inventor should retain IP rights. Whether Notification Nos. 117/163 has such self-executing power is unclear. As noted in the above text, Notifications do not have, on their face, the force of law. But even if this formal characterization is accepted, it could be argued that Notification Nos. 117/163 is a service regulation or other stipulation that effects an automatic transfer of patent rights to the university and the nation under Japanese Patent Law. Section 35(2) of this law recognizes that a service stipulation/regulation can provide—in advance—that the right to obtain a patent or the patent right shall pass to the employer. Patent Law, *supra* note 120, at § 35(2).

However, if the issue of national versus inventor ownership can be resolved in the inventor's favor, then the lack of a formal transfer agreement from inventor

Do available statistics provide evidence of extensive under-reporting of Commissioned or Joint Research discoveries? Unfortunately, nationwide data, which show a dramatic increase in Commissioned Research funding and in patent applications for Commissioned or Joint Research inventions, shed little light on this issue, because they do not separate privately funded from government-funded projects, nor do they include licensing data.¹⁴³ Data from the University of Tokyo show that in 1998, private companies provided about 300 million yen (approximately 2 million USD) for Commissioned Research (135 projects) and about 550 million yen (approximately 3 million USD) for Joint Research (approximately 100 projects) in the University of Tokyo, reflecting a steady upward trend for both types of research.¹⁴⁴ However, the number of University of Tokyo patent applications attributable to privately sponsored Commissioned or Joint Research inventions does not show an upward trend. Instead, between 1996 and 2000, it averaged about three per year.¹⁴⁵ This suggests that the number

to sponsor should not undermine the validity of the assignment. Japanese Patent Law §§ 33 and 34 create a rebuttable presumption that assignments of inventors' patent application rights are valid, even without a written assignment agreement. An inventor can challenge this presumption during examination proceedings at Japan's Patent Office ("JPO"), but only prior to publication. Patent Law, *supra* note 120, at §§ 33, 34. Publication of the application eighteen months after the filing date is a novelty bar against the inventor or any alternative assignee filing a competing application.

¹⁴³ See *infra* § 3.1.3.2 for a discussion of government-funded Commissioned or Joint Research.

¹⁴⁴ Unpublished data from the University's Office of Cooperative Research (1999) (on file with author).

¹⁴⁵ 2001 data from the University of Tokyo's Invention Committee show that for the five-year period 1996-2000, fifty-six *Commissioned Research* inventions were reported to the Invention Committee with the intention of filing patent applications. The Invention Committee data does not identify the sponsors. However, they do indicate whether patent applications were filed either: (a) solely in the name of the University of Tokyo, or (b) jointly with either the sponsor or an inventor who intended to assign his rights to the sponsor. Since industry sponsors almost always want to co-apply for patents that may have commercial value, the number of jointly-filed patent applications, seven, is an upper limit on the number of applications for inventions arising under privately sponsored Commissioned Research. During this same period, the total number of *Joint Research* inventions by University of Tokyo faculty was nine. All of these applications were filed jointly by the University of Tokyo and the sponsors, private companies in most cases. Thus, for the five-year period 1996-2000, the total number of Japanese patent applications for University of Tokyo inventions arising under Commissioned or Joint Research was sixty-five (fifty-six Commissioned and nine Joint), of which, at most, sixteen arose under industry-sponsored research and were of commercial interest to the sponsors, for an average of three industry-sponsored Commis-

of patents per project (or unit of funding) is falling, which in turn suggests either under-reporting of inventions or declining innovativeness of such research.

In contrast, anecdotal surveys suggest that, at least in certain technical fields, the number of patents filed by companies that list university researchers as inventors is quite high.¹⁴⁶ Taken together this data corroborate what the Author hears consistently in discussions with university scientists, namely, that many patentable discoveries arising at least in part under Commissioned or Joint Research are not attributed to such research. Rather, because of the perceived limitations on IP rights, researchers take advantage of various opportunities to attribute inventions to funding sources such as "Donations" where the government has no ownership rights, or to the sponsoring companies' own research.

3.1.2.1.2. *Administration and Flow of Funds*

As noted above, Commissioned or Joint Research funds must be disbursed via the MOF. Over the past two years, restrictions on the disbursement of these funds have been rationalized. By virtue of the 2000 Law to Strengthen Industrial Technology,¹⁴⁷ projects can be approved and funding can begin any time during the year, not just at the beginning of a fiscal year (April 1) as was the case before passage of this law. Thanks to this law and Notification,¹⁴⁸ contracts for multiple-year projects up to five years can be negotiated. Before the advent of multiple-year contracts, a separate contract for each fiscal year had to be concluded. MOF bureaucrats had to approve each year's contract, and the approval process usually took several months. Therefore, if a company sent Commissioned Research funds to the MOF on April 1st, it might have been June or July before the MOF would disburse the funds to the recipient university. Each year there would be a "black-out" window from mid-February until at least June during which funds were not available. Now, the only significant "black-out" window

sioned or Joint Research inventions filed annually.

¹⁴⁶ See discussion *infra* § 3.1.2.2.

¹⁴⁷ *Sangaku Gijutsu Ryoku Kyouka Hou*, Law No. 44 of 2000, (in Japanese), available at <http://www.houko.com> (last visited May 7, 2003).

¹⁴⁸ Monbusho Notification No. 11-1 of 2000, *Pertaining to Flexibly Handling Commissioned Research Agreements and the Like*, Director of the Science and International Affairs Bureau, Research Assistance Division, (Mar. 31, 2000).

is at the beginning of the project when the MOF approves the entire multiple-year project. However, Commissioned or Joint Research funds still must be earmarked for each year and must still be disbursed year by year. Delays of up to a month occur as the MOF bureaucrats approve each yearly project.

In theory, the 2000 Law to Strengthen Industrial Technology allows rollover of unused funds to subsequent years. However, discussions with university administrators suggest that MEXT and MOF officials still require that the company and university researchers justify why actual expenditures did not meet budget projections, and rollovers are still rare. As a result, wasteful end-of-fiscal-year spending still occurs as researchers try to use up funds earmarked for each fiscal year.

3.1.2.1.3. *Personnel Expenses*

Another limitation on the use of Commissioned or Joint Research funds concerns personnel expenses. The long black-out periods prevented use of these funds to pay salaries or stipends. In addition, there were concerns that students and postdoctoral researchers should not become de facto employees of companies and their work on company-funded projects should not interfere with their academic studies. Fee-for-service payments were permitted, if line items for personnel expenses were included in Commissioned or Joint Research contracts. However, at least in the case of graduate students and postdoctoral researchers, approval from the department or the center director was needed and the maximum reimbursement was 1100 yen (about seven dollars) per hour, twenty hours per week.¹⁴⁹ Only a few professors used such funds for personnel expenses.

In March 2001, the MEXT issued a Notification that substantially liberalized policies regarding use of Commissioned or Joint Research funds for personnel expenses.¹⁵⁰ This Notification created the designation of "university-industry-

¹⁴⁹ Author's Conversations with University of Tokyo officials (May 2000) (on file with author).

¹⁵⁰ Kokuritsu daigaku nado ni tsuite kigyō tonō kyōdō kenkyū, jutaku kenkyū ni jugyō sure hijōkin shoku-in no tori-atsukai ni truite [Concerning the Handling of Non-Permanent Employees Engaged in Joint or Commissioned Research with Companies in National Universities], Notification No. 12-276, MEXT Research Promotion Bureau, (Mar. 29, 2001) (also designated as Notification No. 12-243 from the Personnel Office of the Minister's Secretariat, MEXT) (in Japanese) (copy on file with author).

cooperation researchers," which can apply to secretaries, technicians, graduate students, and postdoctoral researchers working on Commissioned or Joint Research in national universities. It allows such persons to be paid as nonpermanent employees. However, they can accumulate retirement benefits under the national social insurance system and be reimbursed for daily commuting expenses, important considerations for most employees. Internal University of Tokyo implementing rules limit the amount of employment hours to eight per day or thirty per week, whichever is less.

The practical effects of this Notification are still unclear. As of January 2002, in the University of Tokyo's entire engineering department, only one researcher was being paid under the authority of this Notification, although this number may increase. The Notification has the potential to enable companies to mobilize support staff and young researchers for company-sponsored projects. On the other hand, various social and institutional factors may limit the number of talented young researchers eager to participate in sponsored research with no guarantee of eventual permanent employment.¹⁵¹

¹⁵¹ First, career opportunities for Ph.D.-level researchers are more limited in Japan than the United States and numbers of Ph.D.s per capita are lower. Unlike the United States where small, often venture capital-financed companies play a major role in technology innovation, large companies still dominate most of Japan's high-technology industries. Most of these still prefer to hire bachelor's or master's degree graduates whom they will train to meet their specific in-house research needs. They usually regard Ph.D. graduates as too focused on narrow basic science issues. Partly as a result, the number of new science and engineering Ph.D. graduates from U.S. universities has been much greater than from Japanese universities, the difference in 1995 being sevenfold. NAT'L SCI. BD., *supra* note 4; Kneller, *Intellectual Property Rights*, *supra* note 2. Second, career considerations in Japanese universities create fewer incentives for graduate students to seek industry funding. The tenured academic civil service reaches down to levels equivalent to postdoctoral researchers in the United States. Moreover, the Japanese system is a narrow hierarchy, modeled on the traditional German "department chair system." The Japanese academic hierarchy, known as a *kouza*, typically consists of one professor (*kyou-ju*), one associate/assistant professor (*jo-kyou-ju*), one assistant professor/instructor (*kou-shi*) and one or two "assistants." Assistants are roughly equivalent to research associates at the Ph.D. candidate or postdoctoral level in the United States—although they occasionally identify themselves as "Assistant Professors" in discussions with foreigners. As mentioned above, none of these persons can supplement their salaries with research project funds. Also, the creation of new *kouzas* as well as personnel appointments within a *kouza* need to be approved by MEXT officials. Therefore, the number of nonstudent university researchers is relatively static. In addition, the research focus and employment/promotion prospects of young researchers is primarily influenced by the *kouza* head. See SAMUEL COLEMAN, JAPANESE SCIENCE

3.1.2.2. *Donations*

In the past and even today, the most common method for companies to support research in national universities has been "Donations," although total Donation levels have been gradually decreasing since 1993. In the late 1990s Donations accounted for about 85% of total industry-sponsored research in national universities.¹⁵² Donations are officially regarded as charitable contributions. Unlike Commissioned or Joint Research funds which must flow through MOF, Donations are made directly to a professor's university research account. Usually, the university takes five to ten percent as overhead. The approval process for Donations under 5 million yen per year (30,000 USD) is simple—a brief written notification to the administrative office of the relevant university department followed by notification to the faculty at one of the twice-monthly faculty meetings. Larger Donations require approval by senior university officials and are rare.

19-44 (1999). Thus, availability of outside funds influences research focus less than in the United States.

Postdoctoral research is not part of the normal science career track, as it is in the United States. In a country that still values lifetime employment and where benefits and status are closely linked with length of service in a particular organization, postdoctoral university research is usually regarded as a non-career-enhancing backwater for persons incapable of obtaining stable longterm employment—unless one already has a career-track position in an outside organization. In 2001, for all fields of science, mathematics, engineering and medicine, there were only eighteen "over doctors" in the University of Tokyo—Ph.D. holders who did not have long-term employment in either the University or outside organizations. *Over-doctor, Over-master Personnel Survey*, UNIVERSITY ANNOUNCEMENTS No. 1226, Dec. 12, 2001, at 7 (official University of Tokyo bulletin). In summary, long-term employment opportunities are more limited for young university Ph.D. researchers in Japan than in the United States, and therefore the increased short-term funding opportunities for Ph.D. students and postdoctoral researchers created by the above Notification may not attract many additional university researchers to industry-funded research.

¹⁵² Donations to national universities in 1996 totalled 48.4 billion yen (300 million USD), Kokuritsu Daigaku Kyoukai [Association of National Universities], available at <http://www.kokudaikyou.gr.jp>. That same year, total industry-sponsored research in Japanese universities amounted to 57 billion yen (360 million USD). Kenneth Pechter, *Measuring the University-Industry Linkage in Japan* (2001) (unpublished Ph.D. dissertation, University of Tokyo) (on file with author). In the case of the University of Tokyo, 1998 Donations amounted to 5.4 billion yen (approximately 32 million USD), while Commissioned or Joint Research funds from private companies amounted to 300 and 550 million yen (approximately 2 and 3.5 million USD), respectively. OFF. COOPERATIVE RES., UNIVERSITY OF TOKYO (Oct. 18, 1999) (on file with author).

Donations traditionally provided more flexibility than Commissioned or Joint Research funds with respect to hiring of personnel. Following liberalization of the use of Commissioned or Joint Research funds, the systems appear similar, but in fact it is still considerably easier to hire secretaries, technicians, and research assistants with Donation funds. Nevertheless, as in the case of Commissioned or Joint Research funds, it is still rare to use Donations to pay stipends for Ph.D. candidates and postdoctoral researchers,¹⁵³ and any salary supplementation by faculty members is prohibited.

The main difference between Donation and Commissioned or Joint Research R&D funding concerns rights to data and IP. It is illegal to condition Donations on promises to perform research according to a specified protocol, provide the donor with research data, or transfer IP rights to the donor because they are regarded as charitable contributions for tax and other official purposes, and because of prohibitions in the National Properties Law¹⁵⁴ and Finance Law¹⁵⁵ against alienating national property. Unlike Commissioned or Joint Research inventions, however, the government has no claim to IP rights. Indeed, Notification No. 163 of 1999¹⁵⁶ excludes Donation inventions from classification as National Inventions by explicitly stating that Donation inventions are outside the scope of the key first criterion of Notification No. 117 of 1978.¹⁵⁷ According to these two Notifications, faculty inventors retain IP rights to Donation inventions and can pass

¹⁵³ In 1996, the University of Tokyo permitted the use of Donation Funds to compensate postdoctoral researchers under age thirty-six for up to twenty hours per week. University of Tokyo Internal Rules Applying to Personnel, Employing Researchers in University of Tokyo Research Facilities (Sept. 10, 1996) (revised Sept. 12, 2000) (on file with author). Since December 2001, the university abolished the age limit on compensable time to thirty hours—the weekly limit for postdoctoral researchers. It also established a separate classification “research fellow” that permits persons under age thirty-six to receive salaries from Donations for up to forty hours of work per week, regardless of their academic degree status. OFF. COOPERATIVE RES., UNIVERSITY OF TOKYO, NOTIFICATION: THE SYSTEM OF UNIVERSITY OF TOKYO RESEARCH FELLOWS (2001) (on file with author). However, as of January, 2002, no graduate students or postdoctoral researchers in the University of Tokyo’s engineering department were employed using Donation Funds.

¹⁵⁴ National Properties Law, *supra* note 128.

¹⁵⁵ Financial Law, *supra* note 106.

¹⁵⁶ Notification No. 163 of 1999, *supra* note 102.

¹⁵⁷ Notification No. 117, in HANDBOOK FOR RESEARCH COOPERATION 1999, *supra* note 99.

these rights as they please to whomever and under whatever terms they choose. They do not have to report the existence of such inventions nor their transfer to anyone; a written assignment document is not necessary for a valid transfer of the inventors' rights.¹⁵⁸

The only data available on the extent of technology transfer via Donation funds is anecdotal, and includes not only inventions arising under them, but also inventions arising under other types of R&D funding.¹⁵⁹ This data suggests that a great proportion of university technology is transferred informally into the industrial sector. For every Commissioned or Joint Research invention reported to national university invention committees, approximately nine inventions are passed informally to industry and usually without being reported to the invention committees. In the field of genetic engineering, nearly forty percent of Japanese patent applications filed by Japanese companies list at least one Japanese university researcher among the inventors, suggesting that, at least in some fields, a significant proportion of company-filed patents are based in part on university discoveries.

Despite the prohibition against placing conditions on Donation Funds, it is a common practice for the donor company and donee professor to sign a two-page memo, *obo-e-gaki* in Japanese, setting forth their shared understanding of their mutual obligations.¹⁶⁰ Generally the *obo-e-gaki* defines the nature of the research, its duration (typically one year), and the amount of support (not more than 5 million yen). It also requires the donee to keep experimental data confidential. The donee is required to report the results rapidly and exclusively to the donor, and allows the donor to approve all manuscripts prior to publication. It forbids the donee from accepting Donations from other donors for the same project. It states that, in principle, the donor will file any patent applications, naming the donee as the inventor, but if the donee approves and the nature of the invention warrants, the donor may add one or more of its employees as co-inventors.

Although both university researchers and companies acknowledge that these terms are probably unenforceable, such *obo-e-gakis*

¹⁵⁸ See text accompanying note 142 *supra* (discussing validity of nonwritten assignments).

¹⁵⁹ See *supra*, § 2.1.2 (discussing licensing). See also Kneller, *Intellectual Property Rights*, *supra* note 2, at 313; Mowery, *supra* note 17, at 315.

¹⁶⁰ Redacted sample in Japanese (on file with author).

continue to be signed. This practice reflects the desire of donor companies to add certainty to a process that legally cannot be made certain. It also suggests that faculty members and companies still perceive that Donation Funds have advantages over the Commissioned or Joint Research funds. For professors, the advantages include more flexible funds that undergird a network of corporate relationships, offering employment opportunities for their students. For companies, the advantages include not only the prospect of receiving full IP rights to university inventions, but also the creation of a network of relationships with university professors that provides information and a source of capable young employees. Nevertheless, companies increasingly express concern about the lack of certainty in their ability to obtain IP rights to Donation-funded inventions and Japanese tax authorities disallowing Donation fund payments as business expenses. Therefore, companies often prefer the certainty of the more limited rights provided under Commissioned or Joint Research contracts.

From a "systems" perspective, the Donation fund system based on university-industry collaboration has at least five significant shortcomings:

- 1) The boundaries of Donation-sponsored research are ambiguous, and therefore donors can expect assignments of many inventions that arise mainly under other sources of support, including government-funded projects.
- 2) Donor companies receive university information and IP rights with no legal incentives to further develop these discoveries. *Obo-e-gakis* hardly ever contain benchmark or due diligence clauses requiring development commitments. They contain no obligation to pay the inventors nor their universities royalties, much less obligations to pay the type of substantial up-front and annual renewal fees common in exclusive licenses those by U.S. TLOs. Although such fees are sometimes cited as evidence of excessive greed on the part of U.S. TLOs,¹⁶¹ the high royalties and stringent development obligations embodied in U.S. universities' exclusive licenses serve an auction function helping to ensure that only companies that are able and committed to making a good faith effort to develop an invention receive

¹⁶¹ See, e.g., Richard Florida, *The Role of the University: Leveraging Talent, Not Technology*, 15 ISSUES IN SCI. AND TECH. POL'Y 67, 69 (1999) (arguing that fees act as creative disincentives to inventors).

exclusive rights to the invention. This auction function is absent under the Donation system.

- 3) No data is available on what inventions are attributed to Donation Funds or what the eventual fate of those inventions are, and thus it is difficult to monitor the existence of industrially relevant discoveries and the effectiveness of technology transfer.
- 4) A typical *obo-e-gaki* lets the donor control research data and publications. At least by U.S. standards, these would be unacceptable restraints on academic freedom. Yet because university researchers are placed in the position of negotiating alone and "under the table" with companies, they are in a weak position to bargain for greater academic rights. Thus a system that intended to empower researchers and provide a safety valve to the strictures accompanying Commissioned or Joint Research ends up making them cede fundamental academic rights to donor companies.
- 5) The informal pass-through of IP rights to donor companies is biased against small companies, especially startup companies in several ways. First, it favors transfers to large companies rather than startup companies since they are more likely to provide Donation funds and hire students. Second, startup companies need a clear unambiguous chain of title to IP rights in order to obtain private venture funding. Because many inventions attributed to Donations in fact arose primarily under other sources of funding and because of the related fact that contractual transfers of Donation inventions are discouraged, a cloud of uncertainty surrounds the chain of title to inventions attributed to Donations. Third, informal pass-through of IP rights to donors can result in related technologies being disseminated to several companies, technologies that if appropriately bundled, could have formed the core of a successful startup company.

3.1.3. *Licensing and Assignments*

3.1.3.1. *Overview*

The previous discussion concerning sponsored research already outlined the basic principles regarding the transfer of

existing inventions from Japanese universities. In particular, in order to determine who should have ownership and transfer rights, it is necessary to determine the source of R&D funding for the invention.

According to Notification Nos. 117 of 1978¹⁶² and 163 of 1999¹⁶³ and the discussion in Section 3.1.2.1.1.2 above, if an invention arises under Donation funding or under a professor's standard research allowance (*Kou-hi*),¹⁶⁴ the inventor may retain ownership and there are no restrictions on how the rights are transferred. If an invention arises under a Commissioned or Joint Research or MEXT Grants-in-Aid (*kaken-hi*) project, or if the inventor chooses to assign her invention to the nation, it is classified as a "National Invention." As noted in Section 3.1.2.1.1.1, if a National Invention arises under Commissioned or Joint Research sponsored by a private company, that company can prenegotiate with the university to co-own the invention or it can receive a preferential license from the university president.¹⁶⁵ But, if a National Invention arises under government project-specific funding (i.e., under a government-funded Commissioned, Joint Research or a Grants-in-Aid project), in most cases the invention is 100% government owned and the Japan Science and Technology Corporation ("JST")¹⁶⁶ a public corporation chartered by the

¹⁶² Notification No. 117 in HANDBOOK FOR RESEARCH COOPERATION 1997, *supra* note 98.

¹⁶³ Notification No. 163, *supra* note 102.

¹⁶⁴ The size of a professor's standard research allowance, *Kou-hi* funding, in Table 1 (*infra*, note 167) probably overestimates its importance in funding innovative research. At least in the Author's experience, a significant proportion (30-50%) of *Kou-hi* funds are not available for discretionary use. Instead, they have already been earmarked by university administrators and senior department professors for "common" uses such as water, electricity, general office and laboratory supplies, laboratory journal subscriptions, and occasionally for a laboratory secretary or computer assistant. Again, in the Author's experience, in a prestigious research center with many additional sources of research funding, it is rare to have to use *Kou-hi* funds to purchase even computers or standard office/laboratory equipment. It would be credible for a professor who is not receiving much other funding to claim that an invention arose under *Kou-hi* funds. But for a researcher from a laboratory blessed with substantial amounts of additional funding, a claim that an invention can be attributed mainly to *Kou-hi* support should be regarded with skepticism.

¹⁶⁵ See *supra* text accompanying notes 116 and 125 (summarizing the terms of a preferential (*yuu-sen*) license and how it is distinguished from other types of licensing).

¹⁶⁶ Japanese: *Kagaku Gi-jutsu Shinkou Jigyō Dan*.

Science and Technology Agency ("STA"), is responsible for patenting and licensing the invention.

This system of ownership and licensing is summarized in Table 1 along with estimates of the magnitude and percentage of each type of funding.¹⁶⁷

¹⁶⁷ Table 1: Ownership of National University Inventions and Transfer Authority as Determined Source of Funds

Type of funding/project	Who owns inventions?	Licensing/assignment authority	Nationwide 1998 funding, billion yen* (million USD)	% total funding (% excluding Kou-hi)
Standard research allowance (Kou-hi)	Inventor	Inventor – no restrictions	143 (\$850)	46 (0)
MEXT Grants-in-Aid (kaken-hi)	Nation/Univ. if applied research	JST, nonexclusive license only	84 (\$510)	27 (50)
	Inventor otherwise ^a	Inventor – no restrictions ^a		
Donations (kifu-kin)	Inventor	Inventor – no restrictions, but transfers of future rights illegal	42 (\$250)	13 (25)
Government-Sponsored Commissioned Research	Nation/Univ.	JST, nonexclusive license only	36 (\$220)	12 (21)
Company-Sponsored Commissioned Research	½ Company ½ Nation/Univ (if by prenegotiated contract)	Co. + Univ. Pres., if nonexclusive or preferential license Co. + U. Pres. + MEXT Minister, if exclusive license	1.4 (\$8.5)	0.4 (0.8)
	Otherwise 100% Nation/Univ	Univ Pres. can grant company preferential license	Rare	
Government-Sponsored Joint Research	Nation/Univ	JST, nonexclusive license only	1 (\$6)	0.3 (0.6)
Company-Sponsored Joint Research	½ Company ½ Nation/Univ (if by prenegotiated contract)	Co. + Univ Pres., if nonexclusive or preferential license Co. + Univ Pres. + MEXT Minister, if exclusive license	3.3 (\$20)	1.1 (2.0)
	Otherwise 100% Nation/Univ	Univ Pres. can grant company preferential license	Rare	

*Estimates are for funds directly available for research (i.e., net of overhead) in National Universities only. See Appendix 2 for calculation methods and data sources.

Since STA merged with Monbusho in 2001 to form MEXT, JST has been within the MEXT organizational structure. JST has one office in downtown Tokyo and another in an outlying suburb. Neither office is close to a major university or the main MEXT offices. In 2000, JST applied for 226 Japanese patents and 116 foreign patents on National Inventions from national universities and MEXT research institutes, and it was granted seventy-eight Japanese and thirty-four foreign patents. The same year, it issued three licenses, all nonexclusive. For the five-year period between 1996 and 2000, JST annually filed on average 134 Japanese patent applications, received sixty-one Japanese patents, and issued 1.6 licenses—all nonexclusive.¹⁶⁸ Although at least one JST official has said it has the authority to grant preferential licenses to National Inventions,¹⁶⁹ in practice JST hardly ever does so officially. The reasons appear to lie both in the National Properties¹⁷⁰ and Finance Laws,¹⁷¹ which require appropriate compensation for alienating national properties, and in a widespread conviction among JST officials that it is inappropriate to allow a private entity to obtain preferential rights to taxpayer funded national property. As mentioned in Section 3.1.2.1.1.1, all royalties were paid to the general account for national universities in the MOF—none were distributed directly to the inventors or their universities.

The overwhelming impression among companies, university scientists, and most government officials is that the JST-National Invention system is not effective in the case of discoveries that require further development and where some degree of exclusive IP rights is necessary to provide private companies with sufficient incentives to invest in such development. In such cases, classification of a government-funded invention as a National Invention is equivalent to the technology slipping into a black hole. This understanding accounts for well-practiced and officially-tolerated efforts to avoid the National Invention classification.¹⁷²

⁴It is difficult to attribute inventions to a project not envisaging practical applications. See *infra* § 3.1.3.3.

¹⁶⁸ Data available at <http://www.jst.go.jp/jst/support-j.htm> (last visited May 7, 2003).

¹⁶⁹ Personal communication between Japan Science and Technology Corporation ("JST") and the Author (1999) (on file with author).

¹⁷⁰ National Properties Law, *supra* note 128.

¹⁷¹ Financial Law, *supra* note 106.

¹⁷² The following example shows both the rigidity of JST's licensing policy and its hesitant attempts to add some flexibility. A professor at a major national

The following sections provide more information on government-funded Commissioned or Joint Research inventions, MEXT Grants-in-Aid, and finally the emergence of university-affiliated technology-transfer organizations, which are beginning to give universities a stake in technology management.

3.1.3.2. Government-Funded Commissioned and Joint Research

Government-, as well as privately funded, Commissioned Research in national universities has increased steadily and dramatically since 1994 when it totaled 7 billion yen (approximately 42 million USD). In 1999, it totaled 45 billion yen (approximately 270 million USD).¹⁷³ If University of Tokyo data are representative of the universities as a whole, then approximately 90% of these funds are from government-affiliated organizations or programs.¹⁷⁴ Such organizations include government-chartered investment corporations such as MEXT's JST and the New Energy Development Organization ("NEDO") of the Ministry of Economy Trade and Industry ("METI" – formerly the Ministry of International Trade and Industry) and GRI's such as the National Institute of Infectious Diseases under the Ministry of Health, Labor and Welfare ("MHLW"). Special government programs that distribute funds as Commissioned Research include the interministerial "Millennium Project" to promote advances in genomics and regenerative medi-

university made an invention with important potential applications in the fields of optics and wireless communication. Although it apparently did not arise under project-specific government funds, the inventor chose nevertheless to assign his rights to the nation, and JST assumed responsibility for patenting and licensing. In 1999, JST licensed the invention to the holding company of a major Japanese industrial manufacturer for 85 million yen (approximately 530,000 USD). The previous year, JST's total revenue from licensing university inventions was 44 million yen (approximately 280,000 USD). *Hyouka kijun motomeru sangaku renkei: "jitsuyouka" tsuyomaru yousei* [University-Industry Cooperation Seeking Valuation Standards in the Quest to Promote "Practical Usefulness"], NIKKEI KEISAI SHINBUN [JAPAN ECONOMIC TIMES] (Dec. 10, 1999) (in Japanese) (copy on file with author). This may still be the largest royalty amount ever received by JST for a license of a university invention. The license was nonexclusive, but JST told the licensee that JST would not license the invention to a competitor without the licensee's permission. Subsequent discussions with JST officials revealed that JST was sensitive that its attempt to convey some degree of exclusivity would become public. They did not seem concerned, or cognizant of the possibility, that the exclusive rights they tried to convey may have been unenforceable or subject to challenge.

¹⁷³ Ministry of Economy Trade and Industry ("METI") data (June 2001) (on file with author).

¹⁷⁴ Office of Cooperative Research Data (Oct. 1999) (on file with author).

cine and MEXT's *Mirai Kaitaku* (Pioneering Research for the Future) Program. Indeed almost all large-scale government-funded R&D projects in universities are classified as Commissioned Research.¹⁷⁵

Although all government-funded Commissioned Research inventions are owned by the nation if judged to have commercial applicability,¹⁷⁶ the precise allocation of ownership rights depends upon which ministry funded the research. In the case of funding from MEXT or its affiliated corporations, patenting and licensing authority lies solely with JST. This is also true in the case of projects funded by METI, the Ministry of Public Management, Home Affairs, Posts and Telecommunications ("MPHPT"), the Environment Ministry, the National Police Agency and the Defense Agency. These ministries and agencies automatically apply the so-called "Japanese Bayh-Dole Law" of 1999 (officially the Law of Special Measures to Revive Industrial Vitality)¹⁷⁷ to permit Commissioned or Joint Research contractors to claim rights to any resulting inventions. Traditionally, because national universities do not have independent legal status, JST manages all patenting and licensing for inventions arising under research commissioned by these ministries and agencies. Other ministries, such as the MHLW and the Ministry of Agriculture, Forestry and Fisheries ("MAFF") usually insist on retaining at least partial ownership over any inventions arising under research they commission, and occasionally insist that their own bureaus manage patent applica-

¹⁷⁵ Obligations to pay overhead appear unclear. Direct communication from the University of Tokyo and METI suggests that many government funding agencies need not make any overhead payments for Commissioned or Joint Research. However, the HANDBOOK FOR RESEARCH COOPERATION and Notification No. 292 of 2001 suggest that the special investment corporations, such as JST and NEDO, under each of the major science and technology ministries should pay 30% overhead on the projects they sponsor, although this percentage can be reduced in case the investment corporation has budget problems. See HANDBOOK FOR RESEARCH COOPERATION, *supra* note 97, at 35. See also Notification No. 292 in HANDBOOK FOR RESEARCH COOPERATION 2002, *supra* note 105. It appears that any such overhead payments can be made directly to the university. The university can then distribute a portion of the overhead payments to the center or department conducting the research. Direct communications from the University of Tokyo to the Author (Mar. 19, 2002). Conversations between METI and the Author (May 14, 2002) (on file with author).

¹⁷⁶ See *supra* § 3.1.2.1.1.2.

¹⁷⁷ Sangyou Katsu-ryoku Saisei Toku-betsu Sochi Hou [Law of Special Measures to Revive Industrial Vitality], No. 31, § 44 (1999) available at <http://law.e-gov.go.jp/cgi-bin/idxsearch.cgi> (last visited May 7, 2003).

tions and licensing. Rights to government-sponsored Joint Research inventions are generally allocated in the same way.

JST patent applications for National Inventions from national universities, consisting mainly of inventions arising under Commissioned or Joint Research, increased from thirty-five in 1996 to 226 in 2000.¹⁷⁸ University of Tokyo Invention Committee data suggests that most of these applications are for government-sponsored projects.¹⁷⁹ Very few, if any, of the government-sponsored inventions have been licensed under royalty-earning licenses.¹⁸⁰

It appears that the policy underlying this phenomenon of increasing patent applications of government-funded inventions is similar to the policy of the U.S. government before 1980 as described by Eisenberg. In other words, JST, acting on the recommendation of university invention committees, applies for patents on government-funded inventions, but with little intent to actually license them. It is simply a means of dedicating the inventions to the public and ensuring that anyone can use them.

However, if some degree of exclusive IP rights is necessary to provide incentives for private investments to improve or market such inventions, either the source of funding must be obscured, or the invention must not be reported, in which case relevant data needs to be passed informally to a particular company that hopefully will complete development. Such an environment of obfuscation is inimical to the open reporting of inventions,¹⁸¹ to putting most transfers on a contractual basis,¹⁸² and to any "champion"¹⁸³ arising to promote the development or utilization of promising early-stage discoveries. Discussions with university researchers suggest that although misattributing government Commissioned or Joint Research inventions to Donations or *Kou-hi* happens fre-

¹⁷⁸ See <http://www.jst.go.jp/jst/support-j.htm> (last visited May 7, 2003).

¹⁷⁹ See *supra* text accompanying note 145 (explaining University of Tokyo's invention committee data).

¹⁸⁰ See *supra* § 3.1.2.1.1.3; *supra* note 172 (discussing the limited royalty earning licenses).

¹⁸¹ Such open reporting of inventions is necessary for the collection of data to assess the number and types of university discoveries.

¹⁸² Putting transfers on a contractual basis is necessary for the collection of data to assess technology transfer and to help ensure fairness in the selection of transferees. It enables the inclusion of due diligence and royalty payment provisions that provide incentives for transferees to make their best efforts to develop the discoveries.

¹⁸³ A "champion" in this context is usually a university TLO, independent technology broker, private venture capital company, or startup company.

quently, some researchers are discouraged by the legal barriers to commercializing government-funded Commissioned or Joint Research and simply write off such discoveries or ignore the commercial implications of such research.¹⁸⁴

3.1.3.3. MEXT Grants-in-Aid (*Kaken-hi*)

As Table 1 indicates, MEXT Grants-in-Aid are the single largest source of project-specific funding for university R&D. These are the bread and butter of Japanese university research support, roughly equivalent to NIH R01 grants for investigator-initiated research proposals or standard NSF grants. Until 1999, many Japanese university researchers assumed that these Grants-in-Aid were outside the scope of the two criteria in Notification No. 117 of 1978 for determining when an invention should be classified as a National Invention,¹⁸⁵ although many felt that this was a "grey area." From 1985 through 1998, on average only one Grant-in-Aid invention per year was classified as a National Invention by the University of Tokyo's Invention Committee, and probably none of

¹⁸⁴ The following anecdote illustrates the frustrations that were encountered by a company trying to develop a government-funded national invention and an inventor who was honest about attributing the invention to government funding. In 1998, a scientist at a major national university working partly under Commissioned Research funding from Ministry of Agriculture, Forestry and Fisheries ("MAFF") made two inventions, both related to immunology and ways to treat or prevent infections in humans or agricultural animals. A Japanese venture capital company contracted with the inventor for assignment of the inventor's ownership rights. It then paid out of pocket five to ten million yen (30,000 to 65,000 USD) to apply for Japanese, European, and U.S. patents. The venture capital company planned to leverage additional private capital to carry forward the development to the point that these discoveries were attractive to pharmaceutical companies. The company, however, did not realize that the Japanese government had an ownership interest in these inventions, believing instead that ownership was divided initially between the inventor and the university as an entity that could independently negotiate transfers of IP. The inventor reported these inventions to the university's invention committee and noted that they were made in part with MAFF funding. A complicated negotiation process between the university and MAFF ensued. The result was a complex division of ownership percentages between MAFF, the university, and the venture capital company, with MAFF allocated the largest share in each invention. The patent applications were amended to clearly show the nation's ownership interest, but the government refused to reimburse the venture company's application costs. MAFF made clear to the venture capital company that their approval would be required for any licenses or assignments of the inventions. To this date, the venture capital company has found no other sources of financing to pursue development, and these discoveries are languishing.

¹⁸⁵ See *supra* § 3.1.2.1.1.2 (detailing ownership of university inventions).

these were licensed. However, in one fell swoop Notification No. 163 of 1999 clarified this grey area by specifying that all Grant-in-Aid inventions are National Inventions, at least all those where the award was for research for applied purposes.¹⁸⁶

The reasons for implementing Notification No. 163 are still unclear, especially since it came just one year after a law supporting the establishment of TLOs that denied the TLOs authority to manage National Inventions, described below. So at the same time the government was trying to support these fledgling organizations, it severely limited the range of inventions they could manage. The director of one of Japan's leading TLOs stated that his TLO will not accept an invention if the inventor says it arose under Grant-in-Aid funds, even if the inventor maintains that the Grant-in-Aid project was for basic research only. In other words, if a commercially valuable invention arises under a MEXT Grant-in-Aid, most TLOs feel it would be risky to argue that the project had purely basic research objectives and the inventor should retain ownership rights.

Nevertheless, available statistics suggest widespread, officially-condoned obfuscation of the funding source of Grant-in-Aid inventions. Appendix 1 shows that the probability is extremely low that the small number of University of Tokyo Grant-in-Aid inventions, relative to the amount of Grant-in-Aid funding, could be due to chance.¹⁸⁷ There seems to be no clear reason why Grant-in-Aid research is less likely to produce patentable inventions than other forms of research, especially *Kou-hi* or government-funded Commissioned or Joint Research. Thus the most likely explanation for the discrepancy noted in Appendix 1 is that Grants-in-Aid inventions either are not transferred at all, or are classified as Donation/*Kou-hi* inventions and transferred directly to companies or to TLOs. Therefore, in issuing Notification No. 163 of 1999, it appears that Monbusho/MEXT took an ideologically motivated step to uphold the principle of national ownership of taxpayer funded inventions, only to then condone or acquiesce to wholesale disregard of that principle.¹⁸⁸

¹⁸⁶ *Id.*

¹⁸⁷ If this analysis were carried out in 1998, the year Notification No. 163 was issued, the discrepancy would be even greater. As it happened, the number of Grant-in-Aid University of Tokyo inventions rose to ten in 2000, but then fell to six in 2001. Preliminary data for 2002 suggests nine for that year.

¹⁸⁸ In this table, Row 1 shows the actual year 2001 numbers for the University of Tokyo patent applications according to source of purported funding for the in-

Note 188 should have been removed during editing. Appendix 1 contains more accurate and up-to-date information on the same topic.

3.1.3.4. TLOs – Disadvantaged Children

Onto an ownership system characterized by a murky and shifting boundary between state and inventor ownership, Monbusho and

vention; applications filed by the University's TLO being a proxy for inventions arising under standard research allowance (*Kou-hi*) and Donation funding. Row 2 shows the expected number of patent applications for each funding category based upon the overall national R&D funding proportions shown in Table 1.

University of Tokyo Patent Applications in 2001 by

Source of Invention Funding

	<i>Kou-hi</i> and Donations (approximated by # TLO applications)	Industry-sponsored Commissioned or Joint Research	MEXT Grants-in-aid	Gov't sponsored Commissioned or Research	Total	One-dimensional chi-square probability (P)
Actual	113	3	5.5	15.5	138	--
Expected assuming all <i>Kou-hi</i> available for research	82.2	2.1	37.3	16.4	138	P<.0001
Expected excluding all <i>Kou-hi</i>	34.6	3.9	69.1	30.4	138	P<.0001

Just from scanning Rows 1 and 2, it is clear that the greatest discrepancy between actual and expected values is the low number of Grants-in-Aid inventions. The probability that this discrepancy between the observed and expected values could be due to chance is less than 1 in 10,000. In other words, there must be some cause for this discrepancy other than mere chance. Indeed, comparison of Rows 1 and 2 probably underestimates the difference between observed and expected numbers of patent applications. A significant proportion of *Kou-hi* funds is not directly available for research. If *Kou-hi* funds are completely excluded, the observed-expected discrepancy becomes even more extreme, as shown in Row 3. Moreover, most TLO officials believe that the number of invention reports they receive still greatly underestimates the total number of inventions made in their universities.

One possible explanation for the actual-expected discrepancy is that Grants-in-Aid research is less likely to produce patentable inventions than other forms of research. While this may arguably be compared to Donations and industry funded Commissioned or Joint Research, it is hard to imagine why Grants-in-Aid research would be less likely to result in inventions than *Kou-hi* or government-funded Commissioned or Joint Research. Thus this data is statistical evidence that a significant percentage of Grants-in-Aid Inventions (and perhaps also government-funded Commissioned or Joint Research inventions) either are not transferred at all or are classified as Donation/*Kou-hi* inventions and transferred directly to companies or to TLOs.

MITI attempted to graft university-affiliated TLOs¹⁸⁹ basically as appendages to individual inventor ownership. Together, these two ministries sponsored legislation passed in 1998¹⁹⁰ to encourage the establishment of university TLOs. The principle points of this legislation and related guidelines are as follows:

- 1) They set forth a procedure for approval of each TLO by the Ministers of both MEXT and METI.¹⁹¹
- 2) Approval allows METI, through the Industrial Structural Improvement Fund,¹⁹² to support each TLO via direct subsidies (currently limited to 20 million yen, approximately 120,000 USD, annually per TLO) and guarantees of bonds issued by the TLO.¹⁹³ However, these funds cannot be used for permanent staff salaries nor for patent application and maintenance payments to outside contract and patent attorneys, the two largest categories of expenses for U.S. TLOs.
- 3) An approved TLO can return royalty earnings to the inventor and the university "via Donations or other means."¹⁹⁴
- 4) An approved TLO can license National Inventions only if it obtains permission of the Minister of MEXT.¹⁹⁵ The Author knows of no such approvals to date, although the case described in Section 3.1.2.1.1.3 was to the same effect.

¹⁸⁹ In Japan, as well as in the United States, TLO has become a generic term for a university technology licensing/transfer/management/development organization. MIT's organization is called the MIT Technology Licensing Office ("MIT TLO"), and this is probably the main origin of the generic abbreviation.

¹⁹⁰ Daigaku nado ni Okeru Gijutsu ni Kan-suru Kenkyuu Seika no Minkan Jigyoe no Iten no Soku-shin ni Kan-suru Hou [Law to Promote Technology Transfer to Private Companies of University Technologies Related to the Research Results] Law No. 52 of 1998 (amended April 2000, when title changed to Daigaku nado Gijutsu Iten Sokushin Hou [Law to Promote the Transfer of University Technologies] available at http://www.mext.go.jp/a_menu/shinkou/sangaku [hereinafter TLO Law].

¹⁹¹ *Id.* at § 4.

¹⁹² Sangyou Kiban Seibi Kikin is a fund established jointly by METI and the Ministry of Post and Telecommunications (a predecessor to today's MPHT) in the 1980s with proceeds from the partial privatization of Nippon Telephone and Telegraph Co. ("NTT"). See <http://www.isif.go.jp> (last visited May 7, 2003).

¹⁹³ TLO Law, *supra* note 190, § 6.

¹⁹⁴ Tokutei daigaku gijutsu iten jigyou no jisshi in kansuru shishin, Monbusho-MITI Bulletin No. 1 [TLO Guidelines No. 1] (Aug. 5, 1998), available at http://www.mext.go.jp/a_menu/shinkou/sangaku/index.htm.

¹⁹⁵ TLO Law, *supra* note 190, § 12.

Thus, the legislation did not change the previously described ownership structure. Barring special action by the MEXT Minister, a TLO can manage only inventor-owned inventions and in those cases only if the inventors voluntarily agree to transfer their rights to the TLO.

The legislation did not give the TLOs a role in clarifying whether an invention belongs to the nation or individual inventors. In other words, the legislation did not attempt to integrate the responsibilities of the TLOs with those of the university Invention Committees. As a rule, TLOs neither seek nor obtain confirmation from the Invention Committees that the inventions they are managing are not National Inventions. As mentioned above, the TLO of the University of Tokyo routinely asks inventors about sources of funding in order to screen out inventions that might be classified as National Inventions; other TLOs probably do the same. However, unlike decisions by the Invention Committees, these determinations have no legal effect, but to the Author's knowledge, they have never been challenged.

The legislation also did not allow for the needs of TLOs to make monetary transfers and to recruit competent staff within the university administrative structures. If the TLOs were to be part of their universities, their personnel would have to be MEXT civil servant generalist-administrators subject to periodic transfers to completely different jobs. Also, under the Financial and General Accounts Laws,¹⁹⁶ it would be problematic for the TLOs to receive royalty payments and to transfer a portion of them to the inventors and their universities.

For these reasons, most TLOs of National Universities were established as for-profit companies whose stock was sold to professors and other individuals willing to invest in them. The TLO law permits TLOs to be for-profit corporations legally separate from universities. The retained royalty income of such corporations is subject to taxation just like that of any other for-profit corporation. The TLOs elected to expose themselves to tax liability in order to obtain freedom over personnel and financial matters. Among National Universities, the most significant exception to this model is the Tokyo Institute of Technology whose TLO was established in 1999 as a special foundation within the institutes. This sheltered it from taxation, but made it more

¹⁹⁶ Financial Laws, *supra* note 106; General Accounts Law, *supra* note 107.

difficult to recruit people from outside the government. Also, as a foundation, it is not able to accept equity in startup companies in lieu of royalties.

Finally, TLOs have no guarantee of institution-wide support from their universities. A case in point is the University of Tokyo's first TLO, which arose from the Research Center for Advanced Science and Technology ("RCAST") and was the first Japanese TLO approved under the 1998 TLO Law. This TLO struggled to build credibility within numerous other centers and departments (many semiautonomous fiefdoms) of the university, particularly in key departments, such as those dealing with medicine and engineering. In 2001, a second university TLO, based in the Institute of Industrial Science ("IIS"), was approved by MEXT and METI. IIS focuses on applied engineering research, which is also a central focus of RCAST research. While the IIS buildings are less than one hundred meters from the RCAST, these two institutions fail to coordinate their technology management efforts because of institutional and personal rivalries, as well as lack of commitment from central university authorities.

In summary, the following factors handicap most TLOs:

- 1) If inventions were accurately attributed to main sources of funding, TLOs would be able to manage only 25-60% of university inventions, based upon the funding levels shown in Table 1. Their ability to manage a larger percentage depends upon officially tolerated misattribution of funding sources.
- 2) Even if TLOs are legally able to manage particular inventions, they are only able to do so if the inventors voluntarily assign their inventions to the TLOs. Officials in several major TLOs have stated that the percentage of inventions that are unreported to either the TLOs or Invention Committees is high. This is true even in universities with stringent reporting requirements. Often professors will assign their less attractive inventions to the TLOs and patent their more attractive inventions themselves or transfer application rights to companies that provide Donations and employ their students (a.k.a. the cherry-picking phenomenon).
- 3) TLOs have to make an unattractive choice between either exposure to corporate income taxation or being subject to burdensome personnel regulations and crippling restrictions on their ability to manage monetary transfers.

Most choose to escape the latter predicament, setting themselves up as for-profit entities separate from their universities.

- 4) TLOs cannot receive financial support from their universities because their universities have neither independent legal status nor budgetary discretion.

The vast majority of U.S. TLOs do not generate profits and a majority of them receive financial support from their universities, usually from discretionary funds under the control of university presidents or vice presidents responsible for technology management and development. At the same time, benefits in terms of creation of new high-technology companies, jobs, and (perhaps more debatably) products are substantial,¹⁹⁷ and the number of U.S. TLOs that have become financially profitable, and return royalties to their universities, is increasing. University support of their TLOs is a long-term investment with potential social as well as financial benefits.

There are several problems with the reliance of Japanese TLOs on government support. As mentioned above, in Japan these funds cannot be used for key TLO expenses. In addition, when a president or vice president of a U.S. university decides to use discretionary funds to support a TLO, the university as a whole becomes committed to its success, and the funding helps to ensure that the work of the TLO is in line with the overall goals of the university. This alignment of goals does not happen when Japanese TLOs receive unconditional subsidies from the Japanese government.

Table 2 summarizes patenting and licensing activity of the most active TLOs.¹⁹⁸

¹⁹⁷ See, e.g., BANKBOSTON, MIT: THE IMPACT OF INNOVATION (1997); Presentation by Lori Pressman and Don Kaiser at the American Association for the Advancement of Science Annual Meeting, Measuring Product Development: Outcomes of Patent Licensing at MIT (describing the successful licensing of MIT patents), at <http://web.mit.edu/tlo/www/pubs.html> (last visited May 7, 2003).

¹⁹⁸ Table 2: Summary of TLO Patents and Licenses as of the end of 2001 (listed in order of number of licenses since approval date*)

Affiliated Universities	Legal Status of TLO (status of universities)	Date Approved (yr/mo)	# Japanese Patents Applications (# approved)	# Foreign Patents Applications (# approved)	# Royalty Earning Patent Licenses

Tokyo, CASTI**	for profit co (nat'l)	1998/12	362 (2)	184 (1)	92
Tohoku	for profit co (nat'l)	1998/12	109 (6)	79 (11)	73
Kyoto, Ritsumei-kan, & other Kansai universities	for-profit co (nat'l & private & local)	1998/12	261 (2)	29 (2)	38
Tokyo Inst. of Tech.	Foundation (nat'l)	1999/8	269 (10)	15 (1)	38
Keio	office in private univ	1999/8	282 (18)	48 (0)	35
Nihon	office in private univ	1998/12	348 (1)	64 (2)	20
Kobe & local universities	Foundation (nat'l & local)	2000/4	85 (0)	9 (0)	20
Yamaguchi & local universities	limited co (nat'l & local)	1999/12	109 (2)	6 (0)	15
Waseda	office in private univ	1999/4	182 (7)	24 (2)	14
Hokkaido & local universities	for profit co (nat'l & local)	1999/12	60 (1)	19 (0)	12
Nagoya & local universities	foundation (nat'l & local)	2000/4	120 (0)	18 (1)	9
Tokyo, IIS***	foundation (nat'l)	2001/8	63 (0)	1 (0)	9
Kyushu	For-profit co (nat'l)	2000/4	132 (0)	9 (0)	8

Source: METI

* Twelve TLOs with fewer than four licenses are not listed.

** Center for Advanced Science and Technology Incubation

*** Institute of Industrial Science

As of the end of 2001, total license revenue for all TLOs was about 340 million yen (approximately 2.3 million USD).¹⁹⁹ As in the case of U.S. TLOs, the Japanese TLOs have various formulas to divide royalty revenue between inventors, the inventors' laboratories or departments, the universities as a whole, and their own operating accounts.

An in-depth assessment of the various TLOs is beyond the scope of this paper. However, considering their handicaps, a handful have made remarkable progress. They have found managers and staff who are proactive in reaching out to researchers (usually through meetings with heads of departments and laboratories) and to potential licensees. They have actively sought foreign licensees and even foreign advice on technology management. To the Author's knowledge, the highest revenue-earning licenses to date tend to be granted to foreign companies. They have emphasized licensing, as well as patenting, although for a variety of reasons they almost always file patent applications before they begin marketing, unlike U.S. TLOs, which may delay filing patent applications until they are relatively sure that have licensees. Some have included due diligence provisions and annual royalty payments in their licenses to ensure that the licensees remain committed to development. Several have participated in the formation of startup companies, licensing the inventors' discoveries back to the inventors' new companies, just as U.S. TLOs do when they assist in forming startup companies. Some have even sought assignments of inventions from research collaborators in other universities to create a package of related inventions, which they then license exclusively to the startup company. Finally, some have taken steps to clarify ownership rights of inventions created by graduate students working in startup company laboratories.²⁰⁰

¹⁹⁹ Direct communication from METI to the Author (Apr. 9, 2003).

²⁰⁰ One example involves a materials science startup company with an off-campus laboratory that attracts students from several universities. The TLO of one of these universities helped resolve questions about ownership of inventions by its students by contracting with these students for assignment of any inventions made in the startup's laboratories. The TLO then licenses these inventions to the startup company. In the case of inventions created by students from other universities, there is lingering uncertainty whether they, their professors, the startup company, or even the universities will have ownership rights.

Still, problems are evident. A widespread tendency prevails among older faculty to manage their own inventions and to transfer them to companies with which they have longstanding ties. Some TLOs are obligated by the local corporations and banks that support them to license preferentially to local corporations. The majority of TLO managers still appear to have no technology marketing and little technology evaluation experience. These managers often take a passive approach to technology transfer, believing their responsibilities are fulfilled when patents are filed. The division, which often borders on rivalry, between TLOs and their universities can give rise to bizarre, frustrating situations as illustrated by the case described in Section 3.1.2.1.1.3. Finally, it is common to hear influential persons, even in government and universities, say that the main goal of TLOs is to make money, and that they are failures if they do not. Much less frequently mentioned are goals such as accelerating the development of technologies to meet public needs and creating high quality jobs.

3.1.4. *Consulting and Other Outside Work*

Japanese university faculty have a long tradition of consulting for private companies.²⁰¹ At least since the end of World War II, these relationships have not been based upon written agreements providing for compensation because this would create outside income, which is prohibited under the Civil Service Law and Regulations.²⁰² Honoraria for lectures and one-time written reports have, however, been permitted. Much paid consulting occurs under this guise. Also, the unwritten quid pro quo for consulting services often includes Donations and employment of students. No data exists on the prevalence of such consulting, much less on how important it is as a mechanism of technology transfer that

²⁰¹ See Takehiko Hashimoto, *The Hesitant Relationship Reconsidered: University-Industry Cooperation in Postwar Japan*, in *INDUSTRIALIZING KNOWLEDGE: UNIVERSITY-INDUSTRY LINKAGES IN JAPAN AND THE UNITED STATES* 234, 235 (Lewis M. Branscomb et al. eds., 1999) (acknowledging that "many university faculty served as technical consultants for corporations in prewar Japan"); Hiroyuki Odagiri, *University-Industry Collaboration in Japan: Facts and Interpretations*, in *INDUSTRIALIZING KNOWLEDGE: UNIVERSITY-INDUSTRY LINKAGES IN JAPAN AND THE UNITED STATES* 252, 254 (Lewis M. Branscomb et al. eds., 1999) (describing specific examples of academics providing advice and guidance to technical industries).

²⁰² Kokka kou-mu-in hou [Civil Servant Law], Law No. 120 (1947), available at <http://law.e-gov.go.jp> (last visited May 7, 2003); Jin ji in ki-soku [Personnel Regulations] (1950).

spurs innovation in industry. However, the Author knows of anecdotal cases where such consulting was very important and suspects it was one of the most important mechanisms of technology transfer in the past and remains important today. However, its effectiveness has been limited by some of the same factors that limit the effectiveness of Donations.²⁰³

In April 2000, the Japanese Diet passed the Law to Strengthen Industrial Technology.²⁰⁴ This landmark legislation not only eliminated many irrational restrictions on industry-funded Commissioned or Joint Research,²⁰⁵ but also opened the door for national university faculty members to openly consult for private companies and even to manage companies, so long as such work was aimed at developing their university discoveries. Following the passage of this law, administrative guidance notifications and amendments to the Personnel Regulations²⁰⁶ have steadily expanded the scope of officially permitted "outside work" (*ken-gyou*), although founder or senior manager/director status is still only allowed in companies aiming to develop the researcher's university discoveries, in TLOs, or in auditing companies. Table 3 summarizes the various categories of approvable outside work and available data on the number of approvals issued to national university researchers.²⁰⁷

²⁰³ See *supra* § 3.1.2.2. (discussing the shortcomings of the Donation system of university-industry collaboration).

²⁰⁴ Sangaku Gijytsu Ryoko Kyouka Hou, *supra* note 147.

²⁰⁵ See *supra* § 3.1.2.1.2 at 373-74 (examining the major aspects of the Law to Strengthen Industrial Technology).

²⁰⁶ Personnel Regulations, *supra* note 202.

²⁰⁷ Table 3: Categories of Outside Work (*Ken-gyou*) Permitted for National University Faculty

Type of work	Approval Required	# of Approvals
Director of a for-profit company to commercialize director's university research	University president, MEXT, and National Personnel authority	71 as of March 2002
Director of TLO	University president, MEXT, and National Personnel authority	31 as of March 2002
Auditor of a for-profit company	University president, MEXT, and National Personnel authority	13 as of March 2002
R&D in a company	University president	45,347 (but many of these involve public, not for profit companies)
Advisor on research/scientific activities	University president	
Advisor on legal and managerial matters concerning a company	University president	

There appear to be few clear limits on outside work. There is vague language to the effect that if a director of a for-profit company finds she needs to devote most of her time to the company and she cannot simultaneously fulfill her duties as a faculty member, then she should take a leave of absence. In the case of persons other than directors, it is clear that outside work does not adversely affect their university responsibilities.²⁰⁸ Also, there is a general prohibition on doing outside work on behalf of a company over one which has authority to award contracts. This probably does *not* prohibit a faculty-director from simultaneously having a Commissioned or Joint Research contract between her university laboratory and her company, although this issue is currently under discussion.²⁰⁹ Specific time limits on outside work have been explicitly abolished, although it is still generally expected that outside work will not take place between 9:00 am and 5:00 pm on normal work days.²¹⁰

Sources:

- 1) Shoku-in no ken-gyou no shou-nin oyo-bi kyou-ka no tetsu-zuki nado ni tsuite [Approval of Outside Work for Civil Servants] (Mar. 29, 2002), available at http://www.mext.go.jp/a_menu/shinkou/sangaku/sangakuc/sangakuc12_1.htm. See also Hashimoto, *supra* note 204; Odagin, *supra* note 204; Personnel Regulations, *supra* note 202 (listing complimentary statutes).
- 2) For the number of approvals in the first three categories, see <http://www.jinji.go.jp/kengyo/f-keng.htm> (last visited May 7, 2003).
- 3) For total number of approvals in the last three categories see the unpublished data from the University of Tokyo.
- 4) MONBU KAGAKU SHOU, KENKYUU SHINKOU KYOKU, KENKYUU KANKYOU SANGYOU RENKEI KA, GIJUTSU ITENN SUISHIN SHITSU, SANGAKU RENKEI JIMU NIUMON [MEXT RESEARCH PROMOTION BUREAU, UNIVERSITY-INDUSTRY COOPERATION OFFICE, UNIVERSITY-INDUSTRY COOPERATION OFFICE GUIDE] (June 2001) [hereinafter SUMMARY NOTIFICATIONS] (duplicating an official summary of various notifications related to university-industry cooperation, especially outside work) (copy on file with author).
- 5) Kengyou ni kansuru mikou kaikabu, kengyou jikan-suu no tori-atsukai ni tsuite (tsuu-chi) [University of Tokyo notification regarding unlisted stock holdings and time limits for outside work] (Dec. 14, 2001) (copy on file with author).

²⁰⁸ SUMMARY NOTIFICATIONS, *supra* note 207, No. 4.

²⁰⁹ Written communication from University of Tokyo to Author (June 28, 2002) (on file with author).

²¹⁰ Kengyou ni kansuru mikou kaikabu, kengyou jikan-suu no tori-atsukai ni tsuite (tsuu-chi) [University of Tokyo notification regarding unlisted stock holdings and time limits for outside work] (Dec. 14, 2001) (copy on file with author).

Restrictions regarding stock ownership appear quite flexible. A blanket restriction on holding non-publicly traded stock in the company has been explicitly abolished.²¹¹ A University of Tokyo notification spells out a few specific circumstances in which pre-IPO stock ownership would be prohibited, but these are clearly egregious conflict-of-interest situations (e.g., a professor-director serves on a drug approval-evaluation committee that will review a drug produced by his own company).²¹² In the case of a director's outside work, holdings of substantial amounts of stock in a third company may also have to be approved by the National Personnel authority if that company has ties with the company in which the researcher is a director.²¹³

When university researchers apply for permission to do outside work, they are required to estimate the amount of time they will spend and the remuneration they will receive. The university president must approve the application, which then will be forwarded to the National Personnel Agency. In the case of directors of for-profit companies and directors of TLOs and auditors, the National Personnel Agency must also approve the applications. The process usually takes a few months and most approvals must be renewed every twelve months.

Approvals for directors and auditors are listed on the Internet along with their estimates of time commitment and income. Therefore, it appears that the policy of MEXT, other Ministries and the National Personnel authority may be to delay issuing specific guidelines until it becomes clear what sort of relationships are evolving between companies and researchers in public institutions. In the meantime, they seem to be permitting a steady stream of outside work relationships. Barely a year after the enactment of the Law to Strengthen Industrial Technology, close to fifty researchers received permission to serve as directors of startup companies. This suggests a commitment at multiple bureaucratic levels to facilitate new company formations by university researchers; that is consistent with a well-publicized government goal of having 1000 university startup companies by July 2004.²¹⁴

²¹¹ *Id.*

²¹² *Id.*

²¹³ SUMMARY NOTIFICATIONS, *supra* note 207, No. 4.

²¹⁴ The goal of having 1000 university-based venture startup companies within three years was announced in June 2001 in the Interim Report prepared by the Headquarters for Industrial Structural Reform and Employment Measures.

3.1.5. *Startup Formation*

By mid-2002, about 435 university startup companies had been formed, with roughly half from national universities and half from private and local government universities. This represents a more than three-fold increase over the number that existed at the end of 2000.²¹⁵ However, in a more complete report on the 251 startup companies tallied just half a year earlier, only seventy-seven (30%) reported sales.²¹⁶ Also, only nineteen of the 251 (8%) reported that they received startup financing from private venture capital and only four reported that such sources accounted for more than 25% of their startup capital. Finally, only a portion of these companies are research- and innovation-oriented. Only one of the university-based life science startups, Angenics, has had an IPO.²¹⁷ One of Japan's major investment and securities companies identified twenty-nine university startup companies pursuing research intensive innovation in biomedicine or biotechnology at the end of 2001.²¹⁸

Although these numbers are small in comparison to the U.S. figures, almost all of these companies have been established within the past five years, suggesting that startup company formation is the most dynamic aspect of Japan's technology-transfer system. Despite some TLOs being active in startup formation, about 85% of university startup companies are still formed by direct transfer of IP rights from inventors to the companies.²¹⁹ In order for these to

See Sangyou koushou kaikaku, koyou taisaku honbu no secchi ni tsuite [Headquarters for Industrial Structural Reform and Employment Measures] (June 26, 2001) available at <http://www.kantei.go.jp/foreign/policy/2001/sangyoukoushou/tyuukan/interim.html>.

²¹⁵ Hitoshi Kikumoto et al., *Daigaku nado hatsu bencha ni kansuru chousa gekka ni tsuite (chuukan happyou)* [Survey of University Startup Companies (mid-year survey)] (Oct. 2002) (unpublished paper on file with author) (updating the report of the same title published annually by the University of Tsukuba.).

²¹⁶ TSUKUBA DAI-GAKU—SENTAN GAKUSAI RYOU-IKI KENKYUU SENTAA, DAI-GAKU NADO BENCHAA NO GENJOU TO KADAI IN KANSURU CHOUA KENKYUU [TSUKUBA UNIVERSITY—CENTER FOR ADVANCED INTERDISCIPLINARY RESEARCH, UNIVERSITY VENTURES—SURVEY OF CURRENT SITUATION AND PROBLEMS] (2002) (copy on file with author). This report, issued in March 2002, counted 251 startups.

²¹⁷ The two other biomedical-focused startup companies that have had IPOs since 2001, Precision Science and Transgenic, have relied on important advice from university researchers.

²¹⁸ Unpublished data from Nomura Research Institute (2002) (on file with author).

²¹⁹ *University Origin Start-Ups Aim at Eventual Listing*, NIKKEI WKLY., Aug. 5,

be valid transfers, the inventions must all have arisen under *Kou-hi* or Donations. It seems that no one has dared to openly question whether this, in fact, is the case.

Among startup companies' greatest challenges are inexperienced management, inability of potential investors to assess the merits of university discoveries, and reluctance on the part of large Japanese companies to turn to them for new technologies. However, the traditional system of IP ownership from Japanese universities also poses problems. The following two cases illustrate how startup companies must navigate between the Scylla of diffuse, uncertain ownership of Donation/*Kou-hi* inventions and the Charybdis of state ownership of Commissioned or Joint Research and Grant-in-Aid inventions.

The first case involves one of Japan's most promising biomedical startup companies. Formed in late 1999, it was blessed with a combination of advantages unique for a Japanese startup:

- a young energetic founder who is not only a respected scientist, but also an entrepreneur inspired by working several years in a leading U.S. university in the company of researchers building their own startup companies;
- unique technologies that have clear medical applications, which are the product of sound scientific research;
- a base in one of Japan's leading national university medical centers;
- a large number of dedicated highly trained researchers;²²⁰ and
- one of the most able startup managers in Japan, whose expertise is now sought by other startup companies.

This company's main problem was that its core technologies were based upon a series of patented inventions that the founder-inventor had passed on informally to about five Japanese pharmaceutical companies under the informal transfer system described in Section 3.1.2.2 above. In order to obtain private funding, the startup company had to retrieve exclusive rights to these inventions. The absence of such rights stymied initial attempts to raise funds. Thanks to the manager's longstanding familiarity with senior pharmaceutical industry managers, the company managed to

2002, at 9.

²²⁰ Japanese physicians voluntarily bind themselves to many years of poorly paid research in order to obtain a Ph.D. necessary for an academic medical career. See COLEMAN, *supra* note 151, at 35 (discussing university politics).

receive assignments-back of all patents covering its core technologies, but at a price: a percentage of its worldwide sales must be paid to each of the five pharmaceutical companies.²²¹ The company has since obtained both corporate and venture consortium funding, its lead products are now undergoing human trials, and it had a successful initial public offering of its stock in 2002. However, this company begins with a significant automatic tap on its income. This case shows how the traditional system of professors retaining rights to their inventions (under the supposition that they arose under Donation or *Kou-hi* funding) and then conveying these rights informally to one or more established companies is inimical to forming a startup company aiming to develop these inventions.

The second case involves a company, established in 2001, which was based upon bioinformatics and genomics technologies from two major national universities and a private inventor. The founders (two national university professors and an independent scientist) are now trying to raise private capital and structure a cooperative research relationship with two universities that will enable the startup company to continue to cooperate with the universities. They decided that funding university research via Donations would not provide sufficient clarity to ownership of future IP rights. However, their potential venture capital investors were extremely concerned that inventions arising under a Commissioned or Joint Research contract would be co-owned by the government. Specifically, they were concerned about the need to obtain permission from the university presidents for sales of software products conveyed as nonexclusive licenses. They were also concerned that any future alliance or merger of the company involving exclusive transfers of IP may have to be approved not only by the university presidents, but also by the Minister of MEXT. In addition, some of the potential investors were also concerned that under Article 73(2) of Japan's Patent Law,²²² the universities would have a theoretical right as co-owners of any Commissioned or Joint Research inventions to exploit the inventions as they wished, even to the extent of competing with the startup company for sales.²²³ The strategy finally agreed upon was to sign Joint Research contracts with the universities, but to

²²¹ Discussions with various pharmaceutical companies with Author (2001-2002) (on file with author).

²²² Patent Law, *supra* note 120, art. 73(2).

²²³ See, e.g., *supra* § 3.1.2.1.1, at 359-365 (discussing the competitive potential).

carefully plan research activities under the contracts so that research conducted in university laboratories would be limited to routine research, while research that might give rise to inventions would be conducted outside the universities with equipment and supplies purchased with private funds. Not only does this scheme impose administrative restrictions on the cooperative research, but it also deprives university researchers of the chance to participate in the most exciting aspects of the research. This example shows how state ownership of university discoveries, even if it is only co-ownership of industry-funded research, can hinder both commercialization and scientific interchange.

These examples are not isolated cases. Rather they illustrate the types of problems caused by the Japanese system of IP ownership and transfer that pose challenges for many startup companies.

3.1.6. *Private Japanese Universities*

As noted under Section 3.1.1, the vast majority of university R&D occurs in national universities. Only a handful of private universities, including Keio, Waseda and Sophia, are internationally recognized research centers.²²⁴ Some other private universities perform sponsored research for nearby companies, and a number of private medical schools conduct clinical trials sponsored by pharmaceutical companies.

Three private universities, Nihon, Ritsumeikan, and Tokai, require assignment to the university of all employee work-related inventions. However, the definition of work-related inventions is less restrictive than in the United States. Inventions made by faculty of these universities using general (i.e., non-project-specific) research funds are usually considered *not* work-related. In other private universities, the circumstances under which employees must assign their inventions to the universities are even more limited.

In the case of company-sponsored research, universities and sponsors can freely negotiate ownership and licensing terms. It appears that universities can usually require employees involved in company-sponsored research to assign their rights to the university or the sponsoring company. In the case of government -

²²⁴ See TOMINAGA KEII, DAIGAKU HYOKA NO KENKYUU [A STUDY EVALUATING UNIVERSITIES] 82 (1984).

sponsored Commissioned or Joint Research, the "Japanese Bayh-Dole Law of 1999" applies.²²⁵ Under this law, some ministries have elected to let all the organizations they commission to do research claim all IP rights to resulting inventions. But other ministries have elected to retain ownership of such inventions or at least the option to retain ownership on a case-by-case basis.

Confusion over ownership rights of private university inventions has occurred. In the late 1990s, a professor at a major private university made an invention using Commissioned Research funds from the "Pioneering Research for the Future" Program of the Japan Society for the Promotion of Science ("JSPS"), one of the two main research funding/investment corporations under Monbusho/MEXT. Apparently unaware of JSPS's ownership interest in the invention, the inventor passed information necessary to apply for a patent to a major engineering company with which he had collaborated in the past. JSPS invalidated the transfer and the company was forced to write a letter of apology to JSPS. The company and JSPS later negotiated a co-ownership agreement under which the company paid royalties to the government. Neither the university nor the inventor has any rights to the royalties.²²⁶

Apparently, in the case of inventions arising under MEXT Grants-in-Aid to private universities, MEXT lets the universities or inventors retain rights, unlike the case of Grants-in-Aid inventions to national universities.²²⁷

3.1.7. *Coming Changes*

3.1.7.1. *General*

Japanese national universities are scheduled to become "National University Corporations,"²²⁸ a type of "independent administrative agency,"²²⁹ in 2004.²³⁰ This will be a major change,

²²⁵ See *supra* text accompanying note 172 (noting that some commissioning agencies assert rights to Commissioned Research inventions while others let the contractees claim rights).

²²⁶ Personal communication from university officials with Author (Apr. 15, 1998) (on file with author).

²²⁷ *Id.*

²²⁸ Japanese: *koku-ritsu dai-gaku hou-jin*.

²²⁹ Japanese: *doku-ritus gyō-sei hou-jin*.

²³⁰ Planning for this change has been underway in earnest since 2000 and the

but while its precise impact on ownership of IP rights and other factors relevant to technology transfer is still under debate, it will probably help correct many of the problems described above. Recent reports by official advisory committees recommend that, as a general principle, the University Corporations should own inventions arising from university research.²³¹ However, this general principle leaves several details unresolved with respect to IP:

- 1) It is likely that a residual category of National Inventions will remain and that these will still be managed by central government bureaus. MEXT has apparently agreed that Grants-in-Aid inventions should be owned by the University Corporations. It has even agreed that inventions arising under Commissioned Research projects sponsored by the JSPS (such as Pioneering Research for the Future projects) should be owned by the universities. However, JST opposes abolition of the National Invention classification and it particularly wants to maintain ownership over inventions arising under some of its programs involving large Commissioned Research projects.²³² Although the JST may be reconciled to letting universities or inventors own even these inventions, proposals are still under consideration to

transformation was originally scheduled for 2003. It is possible it will be postponed even further.

²³¹ Kagaku gijutsu-gaku-jitsu shingi-kai [Science Advisory Committee of MEXT] in Koku-ritsu dai-gaku hou-jin (ka shou) in okeru san-gaku-kan ren-kei no ari-kata ni tsuite (shingi kai no gai-you); [Recommendations on Industry-University-Government Cooperation in National University Corporations] (Dec. 11, 2001) available at http://www.mext.go.jp/b_menu/shingi/gijyutu/gijyutu8/gaiyo/011201.htm.

²³² These programs include the Core Research for Evaluational Science and Technology ("CREST") program, which funds large-scale biomedical research projects and whose 2000 budget was 29 billion yen (approximately 180 million USD). See <http://www.jst.go.jp/crest/>. The Precursory Research for Embryonic Science and Technology Project is also included, which provides generous project grants to young researchers, as well as the Exploratory Research for Advanced Technology ("ERATO") program to fund pioneering innovative research, usually in universities. See <http://www.jst.go.jp/presto/>. Ironically, JST and JSPS are both research investment corporations under MEXT. Before the STA and Monbusho merged, JST was STA's investment corporation while JSPS was Monbusho's. Both JST and JSPS bring their parent corporation's administrative styles and philosophies to the newly created MEXT. In addition, because JST has had technology management responsibilities that extending even to other ministries, it is reluctant to see responsibilities diminished in its home ministry, MEXT. See discussion *supra* note 96. See also discussion *supra* § 3.1.2.1.1.1.

let JST retain co-ownership over some of the inventions it funds. In this case, JST will have veto power over any licenses. How JST might exercise this veto power is unclear. Also unresolved is ownership of IP that will be commissioned by ministries such as MAFF and MHLW, and ministries that do not implement the so-called Japanese Bayh-Dole law to automatically allow commissioned organizations to claim IP rights.²³³

- 2) Even if universities have the right to claim a large portion of inventions, how they will manage the inventions and the future role of the TLOs is still not clear. Although the University Corporations will have some independence over personnel issues, they will largely inherit present administrative staff whose career paths and salary scales may still be linked to the MEXT personnel system. At least in the eyes of some TLO officials, these administrators would not be suitable technology managers. Many TLOs do not want to be absorbed into the administrative structure of the University Corporations because they feel their personnel and technology management decisions would be bureaucratically constrained. So although the University Corporations may end up with ownership rights, administrative personnel and procedures may change little, and many TLOs may want to remain separate organizations. However if they succeed, they may have to negotiate with their universities for assignments of inventions, and the legal and financial relationships with their universities will have to be worked out. It seems clear that independent TLOs will be able to receive either assignments or exclusive licenses.²³⁴ An alternative mechanism under discussion is for the TLOs to act as trustees for the IP of their universities, but current regulations allow only banks and securities companies to act as trustees of IP.²³⁵

²³³ Law of Special Measure to Revive Industrial Vitality, *supra* note 177.

²³⁴ Independent TLOs will also be able to receive *sen-you* licenses that function almost like assignments. See *supra* note 124 (describing various forms of licenses).

²³⁵ *Trust Business to Handle Work Related to Intellectual Property*, NIKKEI WKLY., Jan. 27, 2003, at 4.

- 3) MEXT has recently authorized the establishment of "Intellectual Property Centers"²³⁶ within all major universities. The purpose of these centers is to improve the management of university IP. It appears that many centers will be based on the law faculties of their respective universities and will not provide much expertise to either business or technology issues—the two fields that are most important to U.S. TLOs. It is not clear how the role of the IP Centers will be coordinated with that of the TLOs. Unfortunately, it appears that there is potential for conflict with patenting and licensing authority. As noted above, some TLOs are hindered by lack of support from their universities and are caught up in a rivalry between groups within their universities. The considerable expertise that some of these TLOs have developed may be squandered and technology transfer stymied by a rivalry between TLOs and the new IP Centers that is an extension of existing rivalries within their universities. In the Author's opinion, the establishment of these centers reflects a pervasive overemphasis in Japan on IP protection as a component of technology transfer, and insufficient emphasis on the need to make such transfers attractive and feasible from business and technical perspectives. In any case, the establishment of these centers coupled with the change to independent administrative status, probably will increase pressure on independent TLOs to be incorporated within their universities.
- 4) Partly out of concern over the issues in Items 1-3 above, some faculty members are strongly advocating that inventors in the new University Corporations be allowed to retain ownership over some of their inventions. They argue that if university administrations or TLOs cannot manage inventions competently, or if the IP Centers and the TLOs cannot work together, it would be better if inventors retained ownership. As noted in Section 3.1.6, the concept of "work-related invention" is narrower in Japanese universities than in U.S. universities. Thus, even if all the invention categories listed in Table 1 are officially designated as belonging either to the University Corporations or to the nation, simply maintaining a narrow definition of "work-

²³⁶ Japanese: *Chiteki zaisan honbu*.

related invention" may allow inventors to retain ownership over a considerable portion of their inventions.

Thus despite grounds for real optimism concerning the next two years, the end result may still be a system where ownership and management authority are both unclear and subject to manipulation.

- Faculty members should no longer be civil servants.²³⁷ Precisely what control University Corporations will have over salaries, promotions, etc. is not clear. It seems doubtful that this change will directly alter the *kouza* system.
- Several position papers advocate increased flexibility in employing researchers with outside research funds, otherwise known as soft money. However, these proposals do not advocate permitting full time permanent faculty (i.e., *kouza* members) to supplement their salaries with sponsored or government research funds. Rather, they speak of increased flexibility to pay expenses for graduate students and postdoctoral researchers and for hiring senior *non-permanent* researchers using outside research funds.²³⁸

3.1.7.2. Predictions

Although it is risky to do so, the Author will offer his own predictions in order to clarify the above discussion. University Corporations will be able to claim IP rights to inventions made under Grants-in-Aid and company-sponsored Commissioned or Joint Research. In theory, they will also be able to claim *Kou-hi* and Donation inventions, but pressure from their faculty and the weakness of many TLOs and university administrations may force them to let inventors retain ownership. In some cases, government funding agencies will let the University Corporations own the Commissioned or Joint Research inventions, but, more often, they will require joint ownership and will preserve a veto over exclusive licenses. Rivalries between TLOs and the new legally oriented IP Centers will be a significant problem in some universities and will

²³⁷ Kokuritsu daigaku nado no dokuritsu gyousei houjin ka ni kan-suru chou-sa kentou kaigi [Committee to Examine the Transformation of National Universities into Independent Administrative Entities], Atarashi "kokuritsu daigaku houjin" zou in tsuite [Plan for the New National University Corporations] (Mar. 26, 2002), available at http://www.mext.go.jp/a_menu/koutou/houdou/index.htm.

²³⁸ *Id.*

contribute to pressure to let inventors retain ownership over some of their inventions. In other words, ownership and transfer authority will still vary according to source of funds, although universities will be able to claim ownership over a substantially larger proportion of inventions than they, or their TLOs, currently claim.

The relationship between the TLOs and their universities will be crucial to the success of technology management under the new system. Most TLOs probably will remain separate from the University Corporations. If the TLOs, the new IP Centers, and the administrative personnel in the University Corporations cooperate closely, and if transfer of invention management authority to the TLOs occurs smoothly, then there is a good chance that the TLOs will become the clear focal point for technology transfer for the new University Corporations. Under such circumstances, there will be pressure from all parties for the TLOs to perform well, and the TLOs will have both the means and the incentives to proactively champion promising technologies. But if cooperation is poor, or if the TLOs are perceived to be incompetent, then the incentive will be to obscure the inventions and incorrectly attribute sources of funding in order to let inventors retain ownership whenever possible. This, in turn, will mean that a large number of transfers will still occur informally, with few development obligations and a continuing absence of data on inventions and transfers. The record of cooperation is mixed so far and does not provide grounds for great optimism.

As for personnel issues, it will probably be relatively easy to pay stipends to graduate students and salaries to postdoctoral researchers from sponsored research funds. The *kouza* system will remain intact for the near future. But parallel to it, a new class of nonpermanent "invited" professors, associate/assistant professors, instructors, and special assistants will arise, who will be hired on one-to-five year contracts and draw most of their salaries from sponsored research funds and special government budget allocations. Transitioning to a permanent status will be difficult, except perhaps for young "invited" researchers. Thus, a two-caste system may evolve, with the lower caste consisting of those whose salaries are paid by sponsored research funds and special government allocations. Rather than the opportunistic behavior observed at all levels of the U.S. academic hierarchy, the future Japanese system may be characterized by the "invited" nonpermanent researchers being preoccupied with finding permanent employment during much of their research tenures.

3.2. Japanese GRIs

This Article cannot give a complete account of technology transfer from Japanese GRIs which in 1998 performed about 1.33 trillion yen (approximately 9 billion USD) of R&D as compared to about 2.09 trillion yen (approximately 15 billion USD) performed by Japanese universities.²³⁹ Instead it will focus on the following three organizations:

- The Institute of Physical and Chemical Science ("Riken"), a large multidisciplinary laboratory established as a special public corporation under STA, now part of MEXT.
- The National Institute of Advanced Science and Technology ("AIST"), a collection of research institutes and centers, formerly directly under MITI, now an Independent Administrative Institution associated with METI.
- The laboratories of the Ministry of Health, Labor and Welfare ("MHLW"), among which the largest are the National Cancer Center Research Institute in Tokyo and the National Cardiovascular Center Research Institute in Osaka.

Sponsored research and licensing at the MHLW laboratories illustrate the "traditional" form of technology transfer from GRIs. Among the major GRIs, Riken has the longest tradition of independent ownership and management of IP. AIST was recently transformed to an independent administrative institution. Thus both Riken and AIST may provide a glimpse of what technology transfer may be like in Japanese universities after they become independent administrative agencies.²⁴⁰

3.2.1. Riken

Riken is one of the STA's flagship basic science laboratories. In addition to research in physics and chemistry, it is one of Japan's leading research institutions in biology, particularly botany, brain research, and genomics. In terms of resources, it is Japan's leading center for proteomics research with facilities using nuclear magnetic resonance to determine the structures of various proteins. The facilities are unrivaled anywhere else in the world.

²³⁹ NAT'L SCI. BD., *supra* note 4, at A-15.

²⁴⁰ Because the Author has less access to administrative and legal documents related to GRIs, more of the information in this Section is based upon interviews than in the case of the previous section dealing with universities.

Under the 1958 law that established Riken, it has the authority to own and manage inventions made in its laboratories.²⁴¹ Riken requires its inventors to report their inventions to a technology management office within Riken. In the mid-1990s, Riken gave its inventors the option to receive a half-ownership interest in their inventions in order to encourage its employees to commercialize their research results. Thus, a substantial proportion of Riken inventions are co-owned by Riken and Riken inventors.

However, in the case of sponsored research, Riken strongly urges its inventors to forgo the option of co-ownership so that IP rights remain entirely within its laboratories. This allows Riken to transfer IP rights more easily to the sponsoring organization or to share rights with the sponsor. Thus, in the case of inventions by Riken researchers arising under industry-sponsored projects, Riken either shares patent application rights with the sponsor as a result of a prenegotiated contract between the sponsor and Riken, or retains complete ownership rights that it licenses to the sponsor. Riken has the authority to issue exclusive licenses, but complete assignments in an invention would require approval from the MEXT Minister. In 2000, Riken received nearly 600 million yen (approximately 4 million USD) in sponsored research from private companies, approximately one-third under Joint Research contracts and two-thirds under Commissioned Research contracts.²⁴²

The same year, it received over 700 million yen (approximately 5 million USD) in Commissioned Research from government-affiliated organizations. Riken also annually receives between 100 million and 1 billion yen in Grants-in-Aid from MEXT, often via JST.²⁴³ JST/MEXT applies the Japanese Bayh-Dole Law²⁴⁴ to Riken.²⁴⁵ Therefore, ownership of Grant-in-Aid inventions, as well as inventions from Commissioned or Joint Research funded by JST and JSPS, remains with Riken and the inventors, or Riken alone if Riken requests the inventors to forgo ownership. However, in the case of inventions made under Commissioned Research from the

²⁴¹ Rika-gaku kenkyuu-shou hou [Riken Law], Data from Riken's Office of Technology Management (Mar. 2002).

²⁴² Riken Law, *supra* note 241. Riken does not permit Donation-sponsored research.

²⁴³ Discussions at Riken (Mar. 20, 2002) [hereinafter Riken].

²⁴⁴ Law of Special Measures to Revive Industrial Vitality, *supra* note 177.

²⁴⁵ Riken, *supra* note 243.

Ministry of Agriculture Forestry and Fisheries or the Ministry of Health, Labor and Welfare, ownership of inventions is divided between Riken and the sponsoring agency on a case-by-case basis.

In 2000, Riken filed applications for 171 Japanese and 203 foreign patents.²⁴⁶ Approximately 40% were filed on inventions

²⁴⁶ Table 4: Riken 2000—Ownership and Numbers of Inventions by R&D Funding Source

Type of funding/ project	Who owns inventions?	Japanese patent applications (%)	Licensing/ assignment authority	R&D funding, billion yen (million USD)	% total funding
General R&D budget	Riken	~86 (50%)	Exclusive OK, sublicensing approvable	66 (\$410)	97
	Inventor and Riken	~17 (10%)	Probably most exclusive		
MEXT Grants-in-Aid	Riken	~0	Exclusive OK	~0.5 (\$3)	0.7
Research commissioned by JSPS, JST & ministries that apply Bayh-Dole	Riken	~0	Exclusive OK	0.7 (\$4.4)	1.0
Research commissioned by MAFF, MHLW	Riken and sponsor	~0	Probably nonexclusive only		
Company-Sponsored Commissioned or Joint Research	Riken	~68 (40)	Exclusive OK, but not assignment, sublicensing approvable	0.6 (\$3.8)	0.9
Total	—	171 (100)	—	~68 (\$420)	100

arising from industry-sponsored Commissioned or Joint Research. This percentage is far in excess of the industry's percentage contribution to Riken's total research budget.²⁴⁷ This suggests that without the restrictions and uncertainty associated with national co-ownership, industry-sponsored research will generate inventions with commercial potential that both sponsor, and that the laboratory will seek to patent. About 10% of Riken's applications were filed jointly in the name of Riken and the Riken inventor. About 50% were filed by Riken alone and arose from Riken's internal R&D budget. Very few, if any, of these inventions were attributed to project-specific government funds (i.e., MEXT Grants-in-Aid or government-funded Commissioned or Joint Research).²⁴⁸

At the end of 2000, Riken had licensed 208 inventions out of a total of over 2000 patents, utility model patents, and pending patent applications.²⁴⁹ Total royalties received that year were 32.3 million yen (approximately 200,000 USD). In the 2001 fiscal year, total royalties jumped to about 75 million yen (approximately 500,000 USD), largely due to a single exclusive license to a U.S. biotechnology company discussed under Section 3.4. About 10% of Riken's licenses are exclusive licenses,²⁵⁰ while the remainder are nonexclusive. Riken has the authority to permit sublicenses.

Riken has so far granted about forty applications for its researchers to engage in outside work (*ken-gyou*). As noted above, outside work can include a range of involvement with private sector companies from simply being a member of a company's

²⁴⁷ Riken's total budget for the 2001 fiscal year was 76.9 billion yen (approximately 500 million USD), composed of net personnel and administration expenses of about 11 billion yen and probably net of Grants-in-Aid and Commissioned or Joint Research funds. See <http://www.riken.go.jp> (providing the public with information about Riken) (last visited May 7, 2003). Therefore, it appears that industry Commissioned or Joint Research (approximately 600 million yen), government Commissioned or Joint Research (approximately 700 million yen), and MEXT Grants-in-Aid (approximately 1 billion yen), together account for only about 3% of Riken's budget.

²⁴⁸ Riken, *supra* note 243.

²⁴⁹ Statistics from Riken (Mar. 20, 2002) [hereinafter Riken Statistics].

²⁵⁰ In Japanese, *ittei kikan doku-sen tsuu-jou jissshi-ken* are time-limited exclusive licenses where Riken retains a noncommercial use right. The time limit is often five to ten years with the option to extend. These are nearly identical to the preferential licenses discussed above in relation to universities. They would also fit within the common definition of an "exclusive license" as used in the United States.

scientific advisory committee to being a president or founder of a company.

As of March 2002, twelve Riken startup companies had been formed. All are headed by Riken scientists who maintain their Riken positions. The founders and other Riken researchers can own stock in the companies. Riken graduate students and postdoctoral researchers can work on research important to the startup companies. Some of the inventions that form the core assets of these companies arose as solely Riken-owned or Riken-plus-inventor-owned inventions that were subsequently exclusively licensed to the startup companies.²⁵¹ However, perhaps a majority of the core patent rights derive from Joint Research contracts between the nascent companies and Riken, which call for co-ownership of the inventions by Riken and the startup companies.²⁵² This suggests that startup companies from Japanese universities probably would leap at the chance to leverage private capital to support research in university laboratories under Joint or Commissioned Research, but for the fact that such inventions would be classified as "National Inventions."²⁵³

If a Riken startup company was to merge with another company, Riken would need to approve the transfer of any jointly-owned patents under Section 73 of the Japanese Patent Law,²⁵⁴ and it would require the renegotiation of any exclusive licenses. Riken officials suggested that while Riken would probably approve such transfers in the case of a merger with a Japanese company, Riken would be hesitant to do so in the case of a merger with a foreign company. Nevertheless, as discussed below in Section 3.4, Riken has shown that it is willing to license exclusively to foreign companies if no Japanese companies are interested in a promising Riken invention.

²⁵¹ Most of these are five-year renewable time-limited exclusive licenses. Riken Statistics, *supra* note 249.

²⁵² Riken, *supra* note 243.

²⁵³ Another explanation is that the startup companies prefer the co-ownership rights they can secure via Joint Research contracts as opposed to the five year exclusive licenses they could secure by simply licensing Riken inventions. In either case, this data suggests that the startup companies look favorably upon Joint Research Contracts as a means to cooperate with Riken and secure satisfactory IP rights.

²⁵⁴ See Patent Law, *supra* note 120, § 73 (explaining the rights of joint patent holders).

3.2.2. AIST

3.2.2.1. Pre-2001

The laboratories under AIST have long been the primary R&D laboratories affiliated with MITI/METI. Prior to 2001, AIST was a part of MITI and encompassed several administrative offices and fifteen research institutes.²⁵⁵ Among these institutes was the Electrotechnical Laboratory that played a major role in noted MITI industrial policy initiatives, such as the "Fifth Generation Computer Program/Consortium," which created a revolutionary supercomputer in the 1980s.²⁵⁶ In 1999, the total budget of all fifteen AIST institutes was about 70 billion yen (approximately 450 million USD), of which roughly 60% was for nonpersonnel research expenses.

As in the case of most other GRIs, AIST inventions were, as a rule, National Inventions. However, private sponsors of Commissioned or Joint Research could negotiate with AIST for co-ownership of Commissioned or Joint Research inventions. In the case of Commissioned Research, the default allocation was 100% ownership to AIST/MITI, but the prenegotiated contract could call for AIST to transfer a portion of its rights to the commissioning company. However, the vast majority of sponsored research agreements have been Joint Research contracts. Here, the basic principle has been that ownership should be divided according to each party's contribution. In case an invention was made entirely by company employees, AIST could, in theory, grant the company full ownership. However, this problem never arose for any invention made in an AIST laboratory.²⁵⁷ In 2000, about 180 patents were issued jointly to AIST and sponsoring companies. At the end of that year an additional 600 joint applications were still

²⁵⁵ The Japanese name for the pre-2001 AIST was *Kou-gyou Gijutsu In* and the AIST laboratories were collectively called *Kou-gyou Gi-jutsu In Kenkyuu Jo*.

²⁵⁶ SCOTT CALLON, *DIVIDED SUN: MITI AND THE BREAKDOWN OF JAPANESE HIGH-TECH INDUSTRIAL POLICY 1975-1993* 46-51, 66-74, 97-104 (1995).

²⁵⁷ If company employees engaged in a Joint Research project with AIST make an invention in the company's laboratories, the company almost always retains 100% ownership of the invention. This is different from the case of CRADA inventions made in company laboratories over which the U.S. government does claim an ownership interest. See *supra* § 2.2.1 (discussing how the "FTTA requires that the government retain a nonexclusive, irrevocable, paid-up license to any CRADA inventions, including those made solely by employees of the CRADA partner").

pending before the Japanese Patent Office.²⁵⁸ Jointly owned inventions accounted for approximately half of AIST's 7700 Japanese and 1500 foreign patents at the end of 2000. This suggests that if inventors do not have the option to retain full ownership by attributing their inventions to Donation funds, many inventions will be attributed to sponsored research projects within the industry.

In the case of AIST inventions made under its own research budget, the AIST inventors could own up to 50% of their inventions if they paid the patent application fees. It is not clear how often this happened. Patenting decisions were made by AIST's Research Administration Division while licensing was handled by the Japan Industrial Technology Association, a MITI-affiliated office in downtown Tokyo. In 2000, about 250 patents were issued to AIST for inventions arising under its own R&D budget, and at the end of that year, an additional 400 applications were still pending before the Japanese Patent Office.²⁵⁹

By the end of 2000, AIST was issuing about thirty to forty licenses annually and had active licenses held by about 150 companies covering about 290 (3%) of its 9200 total patents. About half of these were licenses of Joint Research inventions to the sponsors, while half were for inventions arising under AIST's own R&D budget. Total license royalties in 1998 were 82.4 million yen (approximately 500,000 USD).

At least in the case of the licenses for non-Joint Research inventions, almost all were nonexclusive. In other words, the same barriers to exclusive or preferential licenses applied to AIST National Inventions that apply to university National Inventions. However, if the AIST inventor were to recommend a particular licensee, AIST would generally not issue a license to any other company. The same process is noted in Section 3.1.2.1.1.2 with respect to licenses of university inventions by JST. Companies often complain that AIST's licensing offices are too slow and bureaucratic in issuing licenses; that is, unless they become involved themselves in recommending licensees through inventors or laboratories. AIST rarely, if ever, granted permission for

²⁵⁸ Written communication from AIST (Oct. 26, 2001) [hereinafter AIST] (on file with author).

²⁵⁹ *Id.*

sublicenses or other IP transfers to third parties.²⁶⁰

In summary, under the pre-2001 system, technology transfer to industry was burdened by some of the same limitations that burdened technology transfer from universities, namely that (1) many of AIST's own inventions were classified as National Inventions and could only be licensed nonexclusively, and (2) even inventions jointly owned by a Joint Research sponsor could not be transferred to a third party. In one respect, the burden was even greater because there was no option to classify inventions as inventor-owned and then pass these inventions directly to companies. Without this informal transfer option, Joint Research contracts became the only mechanism for companies to obtain some degree of exclusivity over discoveries originating in AIST laboratories. This explains why the number of patent applications, issued patents, and licenses are so impressive compared to the

²⁶⁰ Table 5: Old AIST in 2000—Ownership of Inventions and Number of Japanese Patents and Licenses

Type of funding project	Who owns inventions?	Licensing/ assignment authority	Patents issued during Year	Patents pending at year end	Total patents at year end (foreign patents)	Total licensed patents at year end
General R&D budget	AIST on behalf of nation	Nonexclusive only, but if inventor recommended particular licensee; AIST would usually not license any other company; no sublicenses	~250	400	~3850 (~750)	145
	AIST/nation and Inventor*					
Company-Sponsored Joint Research (Commissioned Research is rare)	AIST/nation and sponsor	No transfers to third parties	180	600	~3850 (~750)	145
Total	—	—	~430	~1000	7700 (1500)	290 royalties ~84 M\ (\$0.5M)

*Inventor needs to pay application fees.

figures for all national universities combined²⁶¹ even though the combined budgets and human resources of AIST are much smaller than those of universities.

The pre-2001 AIST shows what the Japanese university system probably would have been like if university inventors could not retain ownership over any of their inventions. Instead of inventions flowing informally to companies via the "inventor retains ownership" route, the number of Joint Research agreements would have proliferated. This is an indication of how great the pressures are to get around a system of national ownership of IP that requires any license of a taxpayer-funded invention to be nonexclusive. It is another indication of the fundamental incompatibility of a system of state ownership of IP rights that forbids exclusive licenses with the realities of a functional technology-transfer system.

3.2.2.2. *Post-2001*

As of April 2001, AIST was reorganized as an independent administrative institution affiliated with METI.²⁶² The new AIST comprises twenty-two research institutes mostly located in Tsukuba Science City outside of Tokyo, twenty-four research centers with a narrower technology focus than the institutes, an advanced computing center, a depository for patented organisms and various research initiatives, collaboration teams and regional collaboration centers, and administrative offices.²⁶³ One of these offices, AIST Innovations, performs TLO functions related to licensing.

Ownership of privately sponsored Commissioned or Joint Research inventions is unchanged from the old system, except that AIST co-owns inventions in its own name, rather than on behalf of METI and the nation. As an alternative to co-ownership by the sponsor, the sponsor can elect to receive an exclusive or nonexclusive license of resulting inventions. If it elects an exclusive license, it must pay patent prosecution costs. Third-party transfers are now possible, but these need to be approved by AIST's TLO, as well the AIST Intellectual Property Office.

²⁶¹ See JST website at <http://www.jst.go.jp>. (last visited May 7, 2003) (stating that only seventy-eight patents and three licenses were issued out of 226 Japanese applications in 2000).

²⁶² New Japanese name: *San-gyou gi-jutsu sou-gou kenkyuu-jo*.

²⁶³ See AIST website at <http://www.aist.go.jp> (last visited May 7, 2003).

Ownership and transfer authority over government-sponsored Commissioned or Joint Research Inventions is determined first by whether the sponsoring agency applies the Japanese Bayh-Dole Law to let AIST claim full ownership rights. If the sponsoring agency does not, then ownership is decided on a case-by-case basis according to the terms of the research contract.

As for AIST inventions arising from projects funded by its own budget, AIST now owns all rights in its own name. Inventors no longer have a co-ownership option. However, they are guaranteed at least 25% of royalty income.²⁶⁴ Decisions on whether to apply for patents are usually made by the directors of individual research units. The actual application process is managed by AIST's Intellectual Property Division, not the TLO, although the TLO can have input regarding issues such as utility.²⁶⁵

The TLO, AIST Innovations, is responsible for marketing and licensing inventions and it can issue exclusive licenses. However, all its licensing decisions must be approved by AIST's Office of Intellectual Property. Thus, the relationship between AIST's Office of Intellectual Property and AIST Innovations may be a harbinger of the future relationship between the IP Centers in National University Corporations and their TLOs, with the TLOs playing a subservient role.

Under the pre-2001 AIST, permission for outside work (including consulting) on behalf of a for-profit company was rarely

²⁶⁴ Currently 50% of royalty income is allocated to the TLO with the remaining 25% to AIST as a whole. After the TLO becomes more financially stable, its share is expected to fall to 25% with the other 25% dedicated to the inventors' research unit. E-mail from Mr. Nagaiwa, AIST, to the Author (Oct. 10, 2001).

²⁶⁵ Table 6: New AIST—Ownership of Inventions and Management Authority

Type of funding/project	Who owns inventions?	Licensing/assignment authority
General R&D budget	AIST (inventors receive > 25% royalties)	Exclusive license and sublicense OK
Company-Sponsored Commissioned or Joint Research	AIST and sponsor	Third-party transfers subject to AIST approval
	AIST	Exclusive license to sponsor OK
Research commissioned by gov't agency that implements Bayh-Dole	AIST	Exclusive license and sublicense OK
Research commissioned by gov't agency such as MAFF or MHLW	Decided project by project	Project by project

granted. However, since the changes in AIST, 146 applications for permission to engage in outside work have been approved. The majority of these probably involve work in other government-affiliated institutions or activities such as serving on the scientific advisory board of a private company. As of January 2002, only four AIST researchers were officially working in for-profit companies to develop their AIST inventions.²⁶⁶ Special approval, from the National Personnel Office, is needed for outside work involving management of a company.

As of January 2002, five startup companies were formed based upon AIST technologies.²⁶⁷ From subsequent Japanese press reports and the Author's own discussions with venture fund managers, it seems certain that more companies are being formed. Venture capital funds regard some of these new startup companies as good investments. These companies are either receiving exclusive licenses to AIST inventions made under AIST's own budget, or rights to co-own any AIST inventions arising under Joint Research contracts with AIST.

3.2.3. MHLW Laboratories²⁶⁸

The MHLW has a number of stand-alone research centers in addition to several major research institutes attached to specialized MHLW hospitals. The largest of the MHLW's research institutes are the National Cancer Research Institute with a budget for the 2000 fiscal year of 32 billion yen (approximately 200 million USD), which is integrated with the National Cancer Center Hospital in Tokyo. The National Cardiovascular Center Research Institute had a budget for the 2000 fiscal year of 24 billion yen (approximately 160 million USD), integrated with the National Cardiovascular Center Hospital in Osaka. All together, the MHLW owns and manages about 270 hospitals nationwide, about 40 of which are capable of participating in clinical drug trials.

As for AIST and Riken, corporate Donation support for sponsored research is not permitted. All sponsored research must be under either Commissioned or Joint Research contracts negotiated between the sponsors and the individual institutions. As in the case of national universities, Riken, and AIST, the

²⁶⁶ AIST, *supra* note 258.

²⁶⁷ *Id.*

²⁶⁸ Before 2001, MHLW was the Ministry of Health and Welfare ("MHW").

sponsoring company can usually prenegotiate the right to co-own any resulting inventions. Probably the majority of Commissioned or Joint Research contracts between private companies and MHLW institutions are for the clinical development of the sponsors' proprietary drugs or medical devices—i.e., for human clinical trials. In 1999, the pharmaceutical industry contributed 3.7 billion yen (approximately 24 million USD) for clinical trials in MHLW hospitals under Commissioned or Joint Research contracts.²⁶⁹ However, the number of patents arising under Commissioned or Joint Research contracts has been low—the cumulative total as of March 2000 was less than ten.²⁷⁰

Inventions in MHW institutions made with the institutions' own research funds were jointly filed by the inventors or the institute directors. In other words, IPR was to be jointly owned by inventors and their institutes. However, only a few institutes have established formal reporting procedures and before about 1998 neither MHW researchers nor administrators paid much attention to IP issues. Only within the past few years have some institutes begun educational programs related to IP.

Table 7 summarizes patenting and licensing activities by individual MHLW research institutes over the most recent two years.²⁷¹

The individual institutes tend to manage IP issues on their own, although they have the option to let JST handle it on their

²⁶⁹ Discussion between MHLW and the Author (Mar. 2000) (on file with author).

²⁷⁰ *Id.* Unlike pharmaceutical companies sponsoring clinical trials in U.S. academic medical centers which seek to patent a variety of novel methods to use or administer medicines developed under their sponsored trials, pharmaceutical companies sponsoring trials in Japanese academic medical centers rarely do this. The Author is not sure whether this reflects a lower tendency by Japanese, as compared with U.S.-European, pharmaceutical companies to seek method-of-use pharmaceutical patents, or different styles of conducting clinical trials in Japanese as opposed to U.S. medical centers, particularly a tendency by the pharmaceutical companies to define protocols for Japanese hospitals so rigidly that there is little chance the clinicians will invent any new methods of use.

²⁷¹ Table 7: Recent Patenting and Licensing by Individual MHLW Institutes

	Patent Applications*	Issued Patents*	Licenses	License Royalties in Yen
2000	38	9	4	6.5 M \ (~\$40,000)
2001	79	6	5	3.1 M \ (~\$20,000)

*Some of these applications were for Commissioned or Joint Research inventions that were to be co-owned by the sponsoring company.

Source: MHWL Data (on file with author)

behalf. All licenses must be nonexclusive and nontransferable. There are initiatives within MHLW, however, to allow companies that sponsor Commissioned or Joint Research in a MHLW institute to receive preferential licenses in lieu of prenegotiated co-ownership.

Since 2000, MHLW institutes have received large amounts of government Commissioned Research funds under the Millennium Project and other large government programs focused on genomics and regenerative medicine. Most of these Commissioned Research funds are dispersed as individual contracts with particular MHLW institutes via the Organization for Pharmaceutical Safety and Research ("OPSR"),²⁷² a wholly owned MHLW corporation and MHLW's equivalent of JST. OPSR also awards extramural research contracts to GRIs under other ministries and also to universities. Inventions that arise under such Commissioned Research generally are managed by OPSR, except in the case of research commissioned by OPSR in universities and non-MHLW GRIs, in which case the IP management procedures of the recipient institution are followed. In any event, if OPSR applies for patents, it retains a partial ownership interest with the inventing institution. If the inventing institution applies for patents, then it is bound to transfer a partial ownership interest to OPSR.

Over the past two years, OPSR-funded research has produced approximately sixty inventions for which patent applications have been filed. Twenty of these have been filed by OPSR itself, presumably because they arose in MHLW laboratories. Ten of these applications arose under Millennium Project funds. Under a combination ownership-license agreement, ownership rights for these ten inventions and probably most future Millennium Project inventions will be allocated 40% to the inventing institute, 40% to OPSR, and 20% to a government-industry consortium, called Genox Research, which was organized by the government to develop and commercialize genome-related discoveries from the Millennium Project. Under this agreement, the respective MHLW institutes and OPSR exclusively license their invention rights to Genox, but reserve the right to cancel the license.²⁷³ Development

²⁷² Japanese: *I-yaku-hin ki-kou*. See The Organization for Pharmaceutical Safety and Research ("OPSR"/Kiko) website at <http://www.kiko.go.jp> (describing OPSR services) (last visited May 7, 2003).

²⁷³ This is a *sen-yuu jisshi ken* license. See Patent Law, *supra* note 120 (describing this type of license).

and commercialization of these inventions by Genox is proceeding slowly. So far, this is the only license OPSR has issued. OPSR is the only MHLW organization with the authority to issue exclusive or preferential licenses.

Apparently similar rules regarding outside work apply to MHLW researchers as well as to national university and AIST researchers. Responses by MHLW to the Author's queries did not reveal whether any startup companies have been formed to develop discoveries by MHLW researchers. Although many of the MHLW hospitals and sanatoriums are expected to become independent administrative organizations in 2004, the main research laboratories will remain directly under MHLW control.

In summary, technology transfers from MHLW laboratories still occur in a traditional manner. Despite having several large research centers alongside major hospitals, levels of patent applications and licensing are low. Sponsored research within the industry tends to be mainly for clinical trials that do not generate new discoveries. One factor underlying this situation is the low level of awareness of IP issues among researchers and administrators. Another possible factor is the inability, under most circumstances, for companies to receive exclusive rights to MHLW inventions. The inability of licensees to obtain exclusive rights may be particularly discouraging because many of the discoveries that might emerge from MHLW laboratories would be related to drugs or medical devices. It seems doubtful that movements to centralize technology management under OPSR are increasing incentives for collaboration with industry.

3.3. Conflicts of Interest

As Japan tries to liberalize its system of university-industry cooperation, conflict-of-interest issues arise that are as significant as those in the United States. The following discussion focuses on universities. Rather than a thorough analysis, the discussion highlights some the main features of this complicated and rapidly evolving issue in Japan.

As the debate about outside work in Section 3.1.5 indicates, a system now exists for university researchers to consult legally for private companies and to be reimbursed, even by transferring nonpublicly traded stock. Under this system, consulting arrangements must be reported and entered into a public database.

These are significant steps towards making consulting more transparent and ethical.

Nevertheless, there are few guidelines about specific types of relationships with industry that raise concerns, particularly issues that are central to current conflict-of-interest debates in the United States. During negotiations for Commissioned or Joint Research contracts, the university scientists are not asked if they have financial or management interests in the sponsoring company. University administrative officials acknowledge that some cases may be problematic, for example, holding significant amounts of nonpublicly traded stock or having a management position in the sponsor.²⁷⁴ Such cases are "under discussion."

Currently there are no special guidelines that apply when researchers have financial interests in companies sponsoring clinical trials. There are no affirmative obligations for university researchers to disclose financial interests in the sponsor companies to special ethics committees, institutional review boards ("IRB"), or patients. Individual clinical researchers have told the Author that they would voluntarily disclose such interests to their IRB, but this is probably not a uniform practice.²⁷⁵

The seeming reluctance of the Japanese government to enact guidelines at this early stage in the expansion of outside work and startup companies is understandable. But until judicial guidelines are in effect, the following risks will increase:

- Scientific objectivity will be undermined in situations where the outcome of research might affect personal or family financial interests.
- Patients' health may be at risk if conflict-of-interest situations arise in the context of clinical trials.
- Researchers holding inside information will manipulate information available to the public and sell their startup company shares at their maximum.
- Graduate students will be urged to work on startup company projects, even when such work is not in the interest of their academic development.

All these problems are potentially compounded by the fact that many of these startup companies are the recipients of IP rights in

²⁷⁴ Written communication from University of Tokyo, RCAST, administrative office to Author (June 28, 2002) (on file with author).

²⁷⁵ See *supra* § 2.1.5. for a comparison to the U.S. situation.

university discoveries that may have been misappropriately classified as belonging to the inventors.

The greatest danger is that a scandal involving many of these issues will arise and the public will assume that technology transfer as a whole is tainted and primarily for the benefit of greedy faculty members. If the scandal involves a clinical trial in which a patient is injured, and the patient's relatives and IRB members claim they should have known in advance about the conflict-of-interest situation, the outcome could be devastating.

Currently, conflict-of-interest issues are addressed prospectively by university administrative personnel only in the narrow context of applications for outside work. Because administrative personnel rotate jobs every two years, it is difficult for them to obtain substantial expertise in conflict-of-interest issues. In addition, they often lack financial information on individual researchers to proactively address potential conflict situations and make individualized decisions.²⁷⁶ As the Japanese universities become independent administrative entities, they should try to develop a long-term core group of persons with expertise in dealing with conflict-of-interest situations.

3.4. Technology Transfer to Foreign Companies

There are few, if any, formal restrictions against transferring university inventions to foreign companies. Not surprisingly, however, conversations with individual scientists, government officials, and heads of technology-transfer offices often reveal a preference to transfer taxpayer-funded inventions to Japanese companies. Nevertheless, many professors and licensing offices are pleased to transfer rights to foreign companies. They note that it is often more difficult to interest Japanese companies in university technologies and that foreign companies are often more generous in sponsoring university research, paying royalties, and more committed to developing inventions. As noted above, some of the highest royalty-earning licenses by TLOs are the ones granted to foreign companies. Also, a recent Japanese press report describes how Riken licensed diagnostic-related single nucleotide polymorphism ("SNP") patents exclusively to a U.S. biotechnology

²⁷⁶ However, conflict-of-interest situations are not always monitored and prospectively addressed in the United States either. See Cho, *supra* note 49 (explaining how many U.S. policies addressing financial conflict of interest lack specificity and uniformity).

company when no Japanese company showed interest. The company agreed to more rapid development commitments and higher royalty payments than most of Riken's Japanese licensees.²⁷⁷

However, METI recently released a new model contract for government agencies to use when funding research under the Japanese Bayh-Dole Law²⁷⁸ that contains a "Japan manufacturing preference" clause modeled on the U.S. manufacturing preference.²⁷⁹ Specifically, if recipients of government-sponsored Commissioned Research want to transfer IP arising from such research exclusively²⁸⁰ to a third party and if that transfer includes rights to the Japanese market, the commissioning ministry must approve the transfer. However, if the third party promises that manufacturing of any IP-protected products or manufacture using any IP-protected methods will occur in Japan, this requirement is waived. METI's recommended approval criteria are not set forth, but in general it hopes to ensure that the nation's interest is preserved in cases of transfers that will involve foreign manufacturing.

As noted above, the Japanese Bayh-Dole law²⁸¹ applies to government-funded contract research in universities, GRIs, or private companies, but various ministries can exercise discretion regarding its application. Currently, only METI, the Ministry of Public Management, Home Affairs, Posts and Telecommunications, the Environment Ministry, the National Police Agency, and the Defense Agency automatically allow organizations with which they have Commissioned Research contracts to retain ownership of any resulting inventions. METI has informed the other government agencies of this change and has recommended that they apply it too.

The immediate effects of this policy change are limited. It has no effect on universities because, as discussed in Section 3.1.3.2

²⁷⁷ Kanako Sahara, *Report: Riken ga Sa-do Wue-bu Sha ni Kyou-you: SNPs Raisensu Kei-yaku no Ura [Riken Supplies Third Wave Technologies (TWT): Behind the SNP License Contract]*, NIKKEI BIOTECHNOLOGY & BUS., Mar. 2002, at 80-81 (on file with author).

²⁷⁸ See Law of Special Measures to Revive Industrial Vitality, *supra* note 177.

²⁷⁹ See 35 U.S.C. § 204(b) (stating the rules of transfer favoring the United States).

²⁸⁰ The model contract uses a general term for "exclusive" license (*hai-ta-teki*). It is not clear whether it would apply to preferential licenses as well as stronger forms of exclusive licenses.

²⁸¹ See Law of Special Measures to Revive Industrial Vitality, *supra* note 177.

above, inventions arising under government Commissioned Research can only be licensed nonexclusively and there are very few such licenses. The most-affected GRI is probably AIST, whose inventions arising under Commissioned Research from METI and the other ministries and agencies listed above are now covered. However, once universities become independent administrative agencies, they will have the authority to license exclusively some, if not most, government Commissioned Research inventions, and therefore such licenses will be affected.

The question remains whether approval will also be needed in the case of licenses of Grant-in-Aid or industry-financed Commissioned or Joint Research inventions. Discussions with METI and MEXT suggest that the answer is probably no.²⁸² However, there is sentiment among some Diet and government officials to require this on the grounds that Grant-in-Aid research is taxpayer-funded and industry-sponsored researchers use taxpayer-funded infrastructure and the work of government employees. METI would prefer informal, flexible, case-by-case self-monitoring by GRIs and University Corporations, rather than the issuances of notifications or guidelines that would result in the central ministries reviewing many individual license applications.

In any case, if universities, GRIs, and government ministries adopt strict criteria to approve licenses involving overseas manufacturing, or if the approval process takes too much time, many foreign companies will be reluctant to cooperate with Japanese universities or GRIs—particularly if Grant-in-Aid and industry-sponsored Commissioned or Joint Research inventions fall within the *de facto* scope of METI's recommendations. It may also discourage some Japanese companies from collaborating with universities, particularly those companies that are moving manufacturing to China and other overseas locations.

As with other aspects of Japan's technology-transfer system, the negative effects will be most severe for startup companies. If a startup company's core technology is based upon exclusive licenses subject to the Japanese manufacturing preference, any strict or time-consuming approval process will substantially diminish its attractiveness as an alliance partner or as an investment opportunity for venture capital—unless its business plan envisages manufacturing only in Japan. It may become

²⁸² Discussions with METI and the Author (on file with author); Discussions with MEXT and the Author (on file with author).

especially difficult to form any startup company aiming to develop biomedical products based upon patents subject to this preference.²⁸³

The reason that there have been few complaints from companies or U.S. universities that the Bayh-Dole U.S. manufacturing preference forecloses licenses being granted to the best development partners is probably due to two factors, neither of which applies to Japan:

- 1) Implementation of the preference is left largely to the discretion of individual laboratories and until now oversight has not been stringent. In contrast, in Japan approval will have to come from the ministry level where implementation probably will be stricter and more bureaucratic.
- 2) Because most U.S. university exclusive licenses are granted to startup companies that have no plan to manufacture outside the United States (because of the early stage of most technologies, but also because of the large size of the U.S. market), U.S. universities have some political leeway to license companies that will manufacture abroad if they appear to be the most appropriate licensees.²⁸⁴ However, most licensees of Japanese university technologies (with the exception of those that are at such an early stage that any commercial products will be covered by derivative patents) will probably want to have the option to manufacture abroad or to sublicense to a company that will want to manufacture abroad.

The Author's own experience in technology transfer at NIH suggests that national manufacturing restrictions or small business licensing preferences have, on at least a few occasions, resulted in the selection of licensees or CRADA partners that are *not* the most

²⁸³ Patent protection tends to be very important for the development of biomedical products; early-stage university patents often still define a biomedical startup company's core technology even after considerable development work has been done.

²⁸⁴ See GENERAL ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL COMMITTEES: TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES 13, 14 (GAO/RCED-98-126) (1998) (allowing companies that are the most appropriate to gain licensing). The NIH has received only a few requests from university grantees for waivers of the U.S. manufacturing preference and has granted most of these. Written communication from NIH to Author (Jul. 18, 2002) (on file with author).

capable companies to develop drugs and medical devices for the public's benefit.²⁸⁵

More broadly, all countries should be concerned that restricting technology transfer according to the nationality of the licensee or the site of manufacturing will lead to the mercantilization of science and technology. In the long run this may have profound negative consequences for free global investment, internationalization of business partnerships, and international scientific interchange.

An in-depth comparative analysis of national benefits provisions is beyond the scope of this Article. However, the approach of the United Kingdom may be a better model for Japan. The U.K. government places a high priority on commercialization of research from U.K. universities and GRIs to generate "maximum benefits in the form of jobs and prosperity for the nation."²⁸⁶ However, taking into account the U.K.'s international investment, trading, and scientific cooperative relationships, a recent government report recommends leaving decisions regarding how to protect and exploit inventions to individual labs.²⁸⁷ In other words, the government has articulated the goal of commercializing publicly financed inventions for national benefit, but allowing individual laboratories to determine how to achieve this goal and what constitutes benefit to the nation.

But even if Japan were to adopt the U.K. approach, the delays inherent in waiting for university administrators to decide which licenses meet a flexible national benefits test may be so long as to effectively foreclose licensing to all except the companies that will

²⁸⁵ For an example of how foreign participation in an important U.S. Department of Energy CRADA triggered intense debate over how to satisfy the requirements of the U.S. manufacturing preference in the 1986 Federal Technology Transfer Act, 37 C.F.R. § 404.5(2), and the larger issue of foreign access to publicly-funded U.S. technologies; see David Lammers, *U.S. Gives OK to ASML on EUV Effort*, EETIMES (Feb. 24, 1999), available at <http://www.eetimes.com> (highlighting the difficulty of cross-border technology transfer); George Leopold & David Lammers, *U.S. Official Raps German Role in Lithography Group*, EETIMES (June 2, 2000), available at <http://www.eetimes.com> (discussing the difficulties faced by technology consortiums).

²⁸⁶ OFFICE OF SCIENCE AND TECHNOLOGY OF HER MAJESTY'S TREASURY, THE GOVERNMENT'S RESPONSE TO THE BAKER REPORT: "CREATING KNOWLEDGE, CREATING WEALTH": REALIZING THE ECONOMIC POTENTIAL OF PUBLIC SECTOR RESEARCH ESTABLISHMENTS (2002), available at <http://archive.treasury.gov.uk/docs/1999/baker.html> (last visited May 6, 2003).

²⁸⁷ *Id.*

manufacture in Japan. Thus, it may be ironic that just as Japan takes meaningful steps to do away with its bureaucratic system of state ownership of IP rights and to give real technology transfer responsibility to individual public laboratories, it implements protectionist policies that may create significant disincentives for companies, especially startup companies, to cooperate with those laboratories. Nonetheless, METI should be commended for modeling the Japanese manufacturing preference on the least restrictive of the U.S. "national benefits" provisions. As noted in Sections 2.1.2, 2.2.1, and 2.2.2, U.S. laws pose more restrictions on licensing to foreign companies or companies that will manufacture abroad, especially with respect to technologies arising in U.S. GRIs.

4. SUMMARY DISCUSSION

4.1. *Is There Really a Problem with the Japanese System?*

If there are problems with the Japanese system of public-private R&D cooperation and technology transfer, they do not involve the lack of linkages. Numbers and rates of co-authorship of papers in academic journals, where at least one of the authors is from a university or GRI and one is from private industry, are comparable to those in the United States.²⁸⁸ Even the total level of private funding for university R&D appears comparable between the two countries.²⁸⁹ The longstanding importance of Donations and consulting agreements have been noted above. These and other forms of academic-industry cooperation, many informal, have also been noted by other authors.²⁹⁰

As for IP ownership and transfer and how they relate to technology commercialization, the diagram in Appendix 3 summarizes in simplified form the key differences between the Japanese and U.S. systems.

To recap several points illustrated by the diagram:

- 1) In contrast to the United States, where ownership rests with universities, in Japan ownership may rest with either the

²⁸⁸ See Diana Hicks, *University-Industry Research Links in Japan*, 26 POL'Y SCI. 361, 377-379 (1993). Kenneth Pechter, *Measuring the University-Industry Linkage in Japan* 124-227 (2001) (unpublished Ph.D. dissertation, University of Tokyo) (on file with author).

²⁸⁹ Pechter, *supra* note 288.

²⁹⁰ Hicks, *supra* note 288. See also Odagiri, *supra* note 201 (documenting close cooperation).

inventors, the central government, or jointly with universities and industry sponsors of Commissioned or Joint Research.

- 2) Only the first possibility, retention of ownership by the inventors, allows for transferable exclusive rights, and thus, only this is consistent with the needs of many startup companies. However, the range of inventions that inventors can officially control is constrained to between roughly 25%-60% of all university inventions.²⁹¹ Increasing this range requires obfuscation of funding sources.
- 3) In the United States, TLOs are involved in the management of most inventions. In Japan, they are often left out of the picture, even when the nation does not have an ownership interest.
- 4) Japanese startup companies cannot leverage private capital to continue university-based research. To do so would require that they enter into a Joint or Commissioned contract with the university, under which the university would co-own any inventions. So far, transfers of inventions co-owned by the nation/university have been difficult. In contrast, U.S. universities routinely give their startup companies permission to sublicense core IP rights originally licensed from the universities.

Nevertheless, it could be argued that Japanese institutions have developed creative and efficient ways around the exigencies of a legal framework that, on its surface, upholds blanket principles of national ownership and nonexclusive access to publicly-funded technology. These methods allow inventors to retain ownership of the vast majority of inventions and thus most inventions can be commercialized and even passed to startup companies. Indeed, the transfer of university discoveries directly from inventors to companies under the guise of Donation or *Kou-hi* research results occurs more quickly and cheaply than the negotiation process for most licenses by U.S. TLOs. The fact that no organization, not even JST, insists on serious investigation into sources of funding for inventions attributed to *Kou-hi* or Grants-in-Aid can be seen as a virtuous triumph of common sense flexibility over dogmatic adher-

²⁹¹ Depending upon the extent to which *Kou-hi* funds support infrastructure as opposed to specific projects, see *supra* note 167, Table 1 (sampling the degrees of control).

ence to the principle of national ownership and to the numerous notifications.²⁹²

However, the threat that many inventions could be classified as National Inventions hangs like the Sword of Damocles over the technology-transfer process. To avoid making the sword drop, it is necessary to obfuscate the sources of funding for inventions and often to hide the existence of inventions. Obfuscation enables all concerned parties to carry on with a charade which is essential for the system to work. But the necessity of obfuscation discourages contractual transfers from inventors to companies, lest the contract reveal the existence of the inventions and the fact that they may not have arisen under Donation or *Kou-hi* funding. Companies that provide Donations are happy to play along with this charade because they do not want contractual obligations to make royalty payments or to meet development benchmarks.

This lack of contractual transfers is one factor that diminishes the incentive to develop early-stage academic technologies. Without contractual obligations, recipient companies have weak obligations to develop the inventions or to pay royalties. Usually they receive publicly funded inventions for "free." In addition, inventors have no right, contractual or otherwise, to royalties. Neither do universities, even though they ostensibly own National Inventions on behalf of the nation.

The net result is that uncertain early-stage, yet potentially promising academic inventions lack any "champion," any person or organization with incentives to fight to increase their chances of development and commercialization. In contrast, in the United States, inventors, university TLOs, venture capital funds, and the managers appointed by those funds often act in overlapping sequence as champions for early-stage academic technologies. All have the legal and institutional authority to do so.²⁹³ All also have

²⁹² This evokes the common distinction made by Japanese people between surface adherence to formal obligations and strictures, *tate-mae*, and what actually occurs, *hon-ne*. In Japanese society, *hon-ne* that is different from *tate-mae* is often acceptable, so long as surface appearances compatible with *tate-mae* are maintained. Nevertheless, the Author does not want to overemphasize cultural reasons for the differences in the U.S. and Japanese technology-transfer systems. Although cultural factors may be important, the main goal of this Article is to show that many of the problems of the Japanese transfer system can be attributed to the legal and institutional framework, and that this framework should be the focus of reform efforts.

²⁹³ Inventors champion their inventions by advising their TLOs on possible uses and licensees, and also occasionally by establishing or advising startup com-

clear financial incentives to champion promising technologies— incentives that available evidence suggests are important to make the technology-transfer process work.²⁹⁴

Japanese TLOs are beginning to serve as champions for some technologies, but they face hurdles that their U.S. counterparts do not, such as those noted in Section 3.1.3.4. They must take part in the charade to obfuscate invention funding sources. Also they are often at philosophical and legal loggerheads with the administrative staffs of their own universities.

But → In industries that rely primarily on large established companies for technology innovation, the Japanese system might suffice. Technology would be transferred from academic laboratories primarily by informal mechanisms and good academic discoveries would be developed. The lack of technology champions and development incentives would be felt at the margin, i.e., in the case of technologies that may have promise but do not fit the established companies' business plans or are not deemed to be worth the development effort and risk. The development of some promising "marginal" technologies would be delayed or barred, but this might also happen in the same industries in the United States, despite entrepreneurial academic inventors and aggressive TLOs. But in industries where venture capital-backed startup companies can play an important role in developing university discoveries, the constraints inherent in the Japanese system may be devastating. The inability to receive any degree of exclusivity to government-funded Commissioned or Joint Research inventions, the inability to transfer rights to Commissioned or Joint Research inventions that even the startup companies fund, and the uncertain "actual" ownership of inventions alleged to be Donation or *Kou-hi* inventions are incompatible with many startup companies' need for clear, exclusive, transferable IP rights. Without clear, exclusive, transferable IP rights, raising private capital and entering into business alliances requiring transfers of exclusive IP rights becomes problematic. In addition, at least in the past, startup companies could not compete with established companies for access to Donation inventions. They did not have the cash to give many

panies aimed at developing their discoveries.

²⁹⁴ See RICHARD JENSEN & MARIE THURSBY, PROOFS AND PROTOTYPES FOR SALE: THE TALE OF UNIVERSITY LICENSING 23-24 (Nat'l Bureau of Econ. Research, Working Paper No. 6698 (1998)) available at <http://www.nber.org/papers/w6698> (last visited May 7, 2003).

Donations to university professors and they could not offer students stable employment. This latter situation is changing because university researchers can now manage their own startup companies and pass rights to ostensibly Donation-funded inventions to their startup companies, either directly or via their TLOs. But the other barriers to startup companies listed at the beginning of this paragraph remain. So, in Japan the ability of private venture capital and startup companies to act as technology champions remains constrained.

How important are private venture capital and venture capital-backed startup companies in promoting the commercialization of publicly funded discoveries? This is an important question requiring further inquiry, and the answer almost certainly varies according to industry. The finding of Kortum and Lerner—that private venture capital-backed companies in various industries are substantially more innovative than established firms in terms of patent production—provides some evidence for the importance of venture capital-backed startup companies in promoting innovation and economic development.²⁹⁵

This Author's research comparing innovation between Japanese and U.S./European pharmaceutical companies shows that the latter rely much more than the former on drug leads obtained from startup companies.²⁹⁶ In the fields of cancer, cardiovascular and infectious disease drugs, a significant majority of drugs in human clinical trials originate in biotechnology startup companies.²⁹⁷ So at least in the field of drug development, large U.S. and European pharmaceutical companies have decided it makes business sense to leave early-stage innovation up to startup companies and academic institutions. But in Japan, the number of biomedical startup companies is very small,²⁹⁸ and most Japanese pharmaceutical companies develop most of their drugs entirely in-house.²⁹⁹

²⁹⁵ SAMUAL KORTUM & JOSHUA LERNER, DOES VENTURE CAPITAL SPUR INNOVATION? 36-37 (Nat'l Bureau of Econ. Research, Working Paper No. 6846, 1998).

²⁹⁶ Robert Kneller, *Autarkic Drug Discovery in Japanese Pharmaceutical Companies: Insights into National Differences in Industrial Innovation*, RESEARCH POLICY [hereinafter Kneller, *Autarkic Drug Discovery*] (forthcoming) (on file with author).

²⁹⁷ Detailed results from Pharmaceutical Research and Manufacturers Association of America ("PhRMA"), PhRMA Annual Membership Survey, 2001 and 2002 survey data. *Id.*

²⁹⁸ *Supra* § 3.1.5.

²⁹⁹ Somewhat surprisingly, they have been able to maintain a respectable stream of new pipeline drugs relying on traditional in-house methods of pharma-

In the field of information technology ("IT"), the Author had identified only two IT startup companies from Japanese academic institutions as of the end of 2000. Moreover, while Unix, Netscape, Lycos, MPEG, and many other IT companies originated in U.S. universities or were developed with significant input from U.S. university researchers, very few Japanese innovations in IT can be traced in a similar manner to Japanese academic laboratories.³⁰⁰

Although comprehensive cross-industry data is lacking, available information suggests the following first hypothesis: Certain industries can benefit more than others from academic research. These industries will be more innovative and competitive in countries that have effective technology-transfer systems including formal (contractual) technology-transfer mechanisms.³⁰¹

Available data also suggests a second hypothesis: In some industries, venture capital-backed startup companies have an advantage over large, established companies in developing new technologies, including academic discoveries.³⁰²

Finally, the analysis of this paper suggests a third hypothesis that links the first two: Formal mechanisms of technology transfer are particularly important for startup companies in industries where startup companies need clear, transferable, exclusive IP rights to academic discoveries. If such industries are also industries where startup companies have an innovation advantage over established firms, these industries will be more competitive in countries with effective formal mechanisms of academic-industry technology transfer.

These hypotheses remain to be confirmed over a range of industries. But if they are, they might explain why many U.S. companies are more innovative compared to their Japanese counter-

ceutical R&D. However, for cutting edge biomedical technologies, they are turning mainly to U.S. biotechnology startup companies. Kneller, *Autarkic Drug Discovery*, *supra* note 296.

³⁰⁰ Robert Kneller, *University-Industry Cooperation in High Technology*, JAPAN INC. at 26-27 (July 2000), available at <http://www.japaninc.net/article.php?articleID=379> (last visited May 7, 2003).

³⁰¹ A related hypothesis is that formal contractual mechanisms are important incentives for academic researchers and administrators to champion technologies by participating in the technology-transfer and development process. The findings of JENSEN & THURSBY, *supra* note 294, provide support, but further studies, particularly in non-U.S. settings, would be helpful.

³⁰² The findings of KORTUM & LERNER, *supra* note 295, provide support, but further studies particularly of academic-based startup companies in non-U.S. settings are needed.

parts, for example, in biomedical and IT industries where U.S. companies rely extensively upon academic research and where startup companies play a prominent role in developing early-stage discoveries. Biomedicine, in particular drug development, appears to be an industry that relies on academic research where startup companies are more innovative, and have a greater need for clear, exclusive, and transferable IP rights. In this industry, the system of university-industry IP transfer may have directly contributed to U.S. competitiveness. IT may be an industry where strong IP rights may not be as important to startup companies, although it does rely on academic research, and IT startup companies are more innovative than established companies. In the case of IT, the formal system of IP rights transfer may not have *directly* contributed to U.S. industry's success (although other aspects of the system of university-industry cooperation certainly did). But it may have *indirectly* contributed to success by creating incentives for university researchers and administrators to effectively promote technology development—largely by promoting startup companies. In contrast, industries such as automobiles and consumer electronics, where Japanese companies are still world leaders in innovation, appear to be industries that do not rely greatly upon R&D input from universities or startup companies.³⁰³ Also these do not appear to be industries where startup companies play a major role in innovation.

Despite the above being only hypotheses, the Author hopes that this Article has shown, using an international comparative analysis, how the legal framework determining IP rights can have an important impact on the vitality of startup companies, the effec-

³⁰³ One factor underlying this phenomenon is the tradition of lifetime employment that still exists in many large technology-based Japanese manufacturing corporations. The following two factors depend upon lifetime employment: (a) the familiarity, loyalty, and insularity that employees acquire from rotating through many parts of a firm during their careers and (b) the accumulation of tacit knowledge within the firm and the ease with which this knowledge is shared throughout the firm. Thus, in industries where innovation can occur best in-house, the tradition of lifetime employment may give large established Japanese companies a competitive advantage. See Masahiko Aoki, *Toward an Economic Model of the Japanese Firm*, 28 J. OF ECON. LITERATURE 1-27 (1990) (detailing lifetime employment); Guido Reger, *How R&D is Coordinated in Japanese and European Multinationals*, 29 R&D MGMT 71-88 (1999) (comparing various research and development regimes); Eleanor Westney, *Changing Perspectives on the Organization of Japanese Multinational Companies*, in JAPANESE MULTINATIONALS ABROAD: INDIVIDUAL AND ORGANIZATIONAL LEARNING 11-29 (Schon Beechler & Allen Bird eds., 1999) (discussing patterns of cooperation).

tiveness of academic-industry cooperation, and the vitality of some industries.

Of course, the legal and institutional framework of IP ownership and transfer is not the only factor determining the effectiveness of academic-industry cooperation. Other factors include the ability of companies to sponsor research in academic laboratories and the ability to mobilize and incentivize academic researchers for projects that have possible commercial potential. These factors were discussed above in depth because they are integral to academic-industry cooperation. But there are additional factors, which can only be listed here:³⁰⁴

- The extent of public support for academic research.³⁰⁵
- The manner in which government support is distributed.³⁰⁶
- Recruitment and promotion in academic laboratories.
- Labor mobility, specifically: (a) its affects on recruitment of personnel for sponsored research and startup companies, and (b) its relationship to the relative importance of (i) building one's own marketable record of accomplishment, and (ii) seeking long-term job security and patronage within a single organization.³⁰⁷
- Family and other social attitudes towards working for a startup company, and social consequences in the case that the startup company fails.
- The availability of government and private capital, as well as related infrastructure (capital markets, attorneys, accountants, mentors, etc.) to support startup companies.³⁰⁸

³⁰⁴ Most of these factors are dealt with in a forthcoming paper by the Author on Japanese biomedical startup companies.

³⁰⁵ Undoubtedly one factor behind the growth of the U.S. biotechnology industry has been the generous, longstanding government support for biomedical research, primarily from the NIH.

³⁰⁶ The U.S. system is based upon relatively transparent peer review centered on competitive, merit-based awards by committees of scientists who are experts in the field of the proposed research. These committees are sufficiently large and balanced to prevent domination of the committee by a few prominent individuals. The Japanese system is less transparent and does not have the same internal checks that the U.S. system has and, as a result, awards are less competitive and more based upon reputation of the applicant and/or his institution.

³⁰⁷ For more on this latter issue of career advancement by building one's own individual record of accomplishments versus staying within one organization and relying on patronage, see Coleman, *supra* note 151, at 34-5 (giving an example from academic medicine).

³⁰⁸ Lack of private investment capital, however, is not presently a major bottleneck to startup company formation in Japan. More details will be provided in a

- Management of venture funds and startup companies.
- The extent to which established companies rely on in-house R&D for innovation versus the extent to which they rely on alliances with universities and startup companies—the former probably being a characteristic of Japanese companies.³⁰⁹
- Tax laws that affect factors such as: (a) incentives for angel investment in startup companies, and (b) the feasibility of stock options as employee compensation.
- The existence of secondary markets for IP so as to decrease the risk of investment in startup companies.

Some of these factors are more important than the system of university IP management. Indeed, it may be impossible for Japanese universities ever to be centers of dynamic research and innovation on par with North American and U.K. universities, so long as Japanese university careers depend upon insider patronage rather than objectively assessed individual merit and a competitive market for research talent. On the other hand, if the IP management framework is not changed to address the problems analyzed in this Article, startup companies in Japan may never be as numerous or innovative as they are in North America and the United Kingdom. Moreover, changing this framework may be relatively easy compared to changing (a) deep-rooted practices of lifetime employment and consequently low labor mobility, (b) careers based upon patronage, and (c) an apparently deep-rooted hesitancy to assess applicants for jobs and research funding competitively and transparently based upon individual merit.

4.2. Prospects for Japan

Since 1998, important reforms have been made to the Japanese system of technology transfer from both universities and GRIs. In the case of some GRIs, the reforms have gone farther than in universities. In Riken and AIST, for example, the legal framework appears essentially similar to that which applies to U.S. universities. Their researchers can even establish and manage their own startup companies, something their counterparts in most U.S. universities may not do.

separate paper.

³⁰⁹ Kneller, *Autarkic Drug Discovery*, *supra* note 296.

National universities are scheduled to become administratively autonomous corporations in 2004. This change will probably result in the universities being able to assert ownership over a considerably larger range of inventions than they currently can. However, their administrative staffs will not be able to manage these rights effectively, at least in the short term. Some of the TLOs will be able to do so, but there is no guarantee of smooth cooperation between TLOs and universities. Also, ownership of IP may still depend on the source of funding because a residual category of National Inventions may remain, and inventors may be able to retain ownership of a significant proportion of their inventions. Thus misattribution of funding sources and direct, noncontractual undocumented transfers from inventors to companies may continue. This, in turn, will undermine TLOs, hinder startup company formation, and ultimately slow development of promising technologies.

As for other challenges to effective university-industry cooperation, some high government leaders seem to understand the fundamental problems of universities and are advocating increased academic competition, freedom from bureaucratic control, abolition of civil servant status for university personnel, allowing dual employment in universities and industry, abolition of seniority-based promotions, and merit-based competition.³¹⁰ It remains to be seen how these far-reaching proposals will actually be implemented in the face of inertia, apprehension, and opposition from some faculty and administrators.

One area in which reforms have been implemented swiftly is the ability of researchers in universities and GRIs to participate in outside work, even to the point of managing their own startup companies. Preapproval and thereafter annual reporting are required, but otherwise, there are few limits on such work. This relatively liberal policy may have merit in view of the disincentives to change jobs or work in startup companies, due to low labor mobility and the system of lifetime employment.

Guidelines to prevent and manage conflict-of-interest situations will have to be developed soon. In addition, particular university officials need to be trained and given authority to deal with conflict of issues. There seems to be few if any grass-roots initiatives to develop appropriate methods to deal with potential con-

³¹⁰ Omi, *supra* note 1.

flict situations. Initiative probably will come from central government bureaucrats.

Finally, as Japan implements its new preference for licensing to companies that will manufacture in Japan, it should be careful not to undo many of the beneficial effects of the reforms now underway. The dangers to Japanese startup companies have already been mentioned in Section 3.1.7, particularly difficulties attracting private investment if the private investors perceive that key technologies cannot be used outside Japan.

4.3. Lessons for all Countries

The number of ownership options for publicly financed academic inventions are limited. Either the inventors, state, research institutions, or companies that sponsor research own and control IP rights. The Japanese system embodies all these ownership structures. Japan's experience with each of these ownership regimes offers cautionary lessons for other countries contemplating changes in their technology-transfer systems, even for the United States, especially when Japan's experience is viewed over the past thirty years and when it is compared with the U.S. experience over the same period.

First, there are perils associated with government ownership of publicly-financed academic inventions, if such ownership implies either patenting and licensing by central bureaucracies or restraints on exclusive IP rights transfers when further private-sector development of inventions is required. The Japanese system of government ownership has produced very few commercially useful patents. Government ownership is inconsistent with the needs of many startup companies and even the needs of many established companies contemplating development of early-stage academic technologies. In Japan, government ownership of university inventions is avoided whenever possible. In GRIs where it is impossible to disguise government-owned inventions as Donation or *Kou-hi* inventions, the number of licensed government-owned inventions is very small. This suggests that without such bypass mechanisms, government-owned inventions that require further development will be difficult to commercialize.

This is not to deny the merit of public ownership of (or more precisely, *open access to*) some publicly funded inventions. Indeed, the types of publicly funded inventions to which exclusive private rights should be granted, as well as the types of industries where

innovation is encouraged by universities conveying exclusive rights, are still matters of open debate. The Japanese experience cautions against blanket prohibitions against granting exclusive rights to such inventions and against the locus of decision making being a central government bureaucracy. In the Author's own experience in technology transfer at NIH, close contact between technology transfer personnel and inventors was extremely important to assess new discoveries and to guide decisions about patenting and marketing. It is hard to conceive how bureaucrats in a central office can be as effective as persons close to the research laboratories.³¹¹ Finally, giving academic institutions the right to own publicly-funded discoveries does not necessarily mean that rights to these inventions will be exclusively held. The PHS/NIH policy that PHS/NIH-funded inventions should be exclusively licensed only if necessary to provide necessary incentives for development³¹² is a policy that probably merits general application to publicly funded discoveries arising in academic institutions.

Second, ownership by inventors may also be problematic, absent an entrepreneurial culture and the infrastructure to help inventors make informed decisions about which companies to transfer their invention and the terms of transfer. The Japanese experience with this ownership system suggests that some inventors will transfer discoveries to companies, but while the technology is still at an early stage so that all the development initiative will be left up to the company. Also, large established companies are most often the recipients. However, the recent rise in startup company formation in Japan suggests that as entrepreneurial culture spreads among academic researchers and as TLOs, incubators and venture capital funds improve, individual inventor ownership can result in effective technology transfer. However, it would be more difficult to enforce any guidelines favoring nonexclusive li-

³¹¹ The history of the British Technology Group ("BTG") is germane to this issue. BTG's predecessor, the National Research Development Corporation, was created in 1949; in 1950, British Treasury Circular No. 5 granted it first rights of refusal on inventions and other IP arising from publicly-funded research. These rights were withdrawn in 1985 in order to give universities more flexibility in technology management and because BTG felt its resources were being spread too thin as the number of university technologies increased. Written communication from U.K. Embassy in Tokyo (June 28, 2002). An assessment of BTG's technology and IP management record during the period before 1985 when it was the sole U.K. organization managing publicly-funded technologies would help resolve this issue.

³¹² See *supra* notes 43, 85, 89 (discussing incentives to invent).

censing under an "inventors retain ownership" system. Thus, allowing inventors to retain ownership of their inventions is probably not the best solution for most countries because of both immature technology-transfer infrastructures and the public interest in limiting exclusive transfers of publicly funded technologies to where the exclusive rights are necessary to encourage development.

Third, co-ownership can also be problematic. In Japan, co-ownership between the nation and the sponsoring company is the most frequent allocation of rights to industry-sponsored Commissioned or Joint Research inventions. In Japan, co-ownership has brought no financial benefit to academic laboratories, yet it has greatly complicated licensing. A better alternative might be to let the research institution or the inventor keep full control of the rights. Then, if licensing should be restricted for policy reasons, special guidelines should be implemented.

Fourth, it may be unwise to make control over academic IP dependent upon the sources of funding for an invention. The Japanese system shows that this allows frequent manipulation, which may ultimately make IP rights less certain and the transfer process less consistent. It may be better to allow research institutions (or individual inventors) claim all IP rights. Thus the policy of most U.S. universities to assert ownership over all industry-sponsored inventions, almost all employee inventions, and most student invention, overreaching as it may seem, may help preserve the overall effectiveness of the technology-transfer system.

Fifth, the U.S. manufacturing preference may not be the best model to ensure that the development of taxpayer-funded discoveries results in benefits to the taxpayers and their nation. Due to unique features of the U.S. economy, and because the preference has not been rigorously enforced, there probably have been few cases of sub-optimal licenses being selected due to the U.S. manufacturing or small business preferences. But when other countries, such as Japan, follow the U.S. model, sub-optimal decisions may become apparent quite soon. The sense of discrimination that this might cause in the United States and third countries may engender more rigorous enforcement of the U.S. provisions and those in third countries. This could lead to a competitive downward spiral in which countries treat scientific research as a mercantile commodity to be hoarded within national boundaries, with significant adverse consequences for business, science, and

health. A more flexible "national benefits test" leaving decisions to the laboratories is a better model.

APPENDIX 1: STATISTICAL ANALYSIS SHOWING THAT THE NUMBER OF GRANT-IN-AID INVENTIONS IS MUCH LESS THAN EXPECTED

In the table below, Row 1 shows R&D funding in each category for the University of Tokyo in 2001.³¹³ Row 2 shows the distribution, according to purported funding source, of the 181 University of Tokyo inventions on which Japanese patent applications were filed in 2001. Here, applications filed by the University's TLOs are a proxy for inventions arising under standard research allowance (*Kou-hi*) and Donation funding. Row 3 shows the expected distribution of the 181 inventions if the distribution had been proportional to amount of funding.

University of Tokyo Patent Applications in 2001 by Source of Invention Funding

	<i>Kou-hi</i> and Donations	Industry-Sponsored Commissioned or Joint Research	MEXT Grants-in-Aid	Gov't-Sponsored Commissioned or Joint Research	Total	One-dimensional chi-square probability (P)
1. Funding (B)	60.9*	1.8	22.7	7.2	92.6	—
2. Actual # of applications	155**	4	5.5***	16.5***	181	—
3. Expected applications assuming all <i>Kou-hi</i> avail. for R&D	119	4	44	14	181	P<.0001
4. Expected applications assuming no <i>Kou-hi</i> avail. for R&D	40	8	101	32	181	P<.0001

* Consists of 51.8 billion yen of *Kou-hi* and 9.1 billion yen of Donations.

³¹³ See THE UNIVERSITY OF TOKYO, TOKYOU DAIGAKU NO GAIYOU 2002 [SUMMARY OF THE UNIVERSITY OF TOKYO 2002] 47-48 (on file with author) (estimating the breakdown between industry- and government-sponsored Commissioned or Joint Research calculated in the same way as in Table 1 and as explained *infra* in Appendix 2).

** Approximated by the number of patent applications filed by CASTI (132) and the IIS TLO (22) in 2001 (source: METI). Also includes one invention voluntarily transferred by the inventor to the university/nation (University of Tokyo Invention Comm. data).

*** One of these inventions was designated as arising under both Commissioned Research and Grant-in-Aid support, so the Author assigned half of it to each of these categories.

Just by scanning Rows 2 and 3, it is clear that the greatest discrepancy between actual and expected values is the low number of Grants-in-Aid inventions. The probability that this discrepancy between the observed and expected values could be due to chance is less than 1 in 10,000. In other words, there must be some cause for this discrepancy other than mere chance. Indeed, comparison of Rows 2 and 3 probably underestimates the difference between observed and expected numbers of patent applications because a significant proportion of *Kou-hi* funds are not directly available for research. If *Kou-hi* funds (totaling 51.8 billion yen) are excluded, the observed-expected discrepancy becomes even more extreme, as shown by comparing Rows 2 and 4.

APPENDIX 2: DERIVATION OF FUNDING ESTIMATES FOR EACH TYPE OF FUNDING/PROJECT IN TABLE 1

Standard research allowance (Kou-hi):

Source: KOKURITSU GAKKOU TOKUBETSU KAIKEI - YOSAN SHITSUMU HANDOBUKKU: HEISEI 10 [1998 BUDGET HANDBOOK FOR THE SPECIAL ACCOUNTS OF NATIONAL SCHOOLS] 205 (1999). In fact, much of this is used for overhead expenses, so the 143 billion yen (approximately 860 million USD) figure significantly overstates its significance as a source of direct research support.³¹⁴

MEXT Grants-in-Aid(Kaken-hi):

Official time series data are available at <http://www.jsps.go.jp/j-grantsinaid>. This data includes Grants-in-Aid to private and local government universities, as well as national universities. A partial breakdown by national, private, and local universities for fiscal year 2002 funding is available at the same URL.

³¹⁴ See *supra*, note 174.

This data shows that of the total 2002 fiscal year ("FY") appropriation of 170.3 billion yen (approximately 1 billion USD), the allocation of 132.7 billion yen between national, private, and local universities was already decided as of April 2002. Of this 132.7 billion yen, 96.5 billion yen (73%) is budgeted for national universities. Of this 96.5 billion yen, 6.4 billion yen (6.6%) is for overhead payments. Therefore, 90.1 billion yen of the 132.7 billion yen is directly available to support research in national universities.

As for the portion of the 2002 FY budget that had not been allocated as of April 2002 (170.3 billion—132.7 billion = 37.6 billion yen), most of this is for large project grants that are probably more heavily weighted towards national universities than other grants. The Author estimates that 85% of this amount, or 32 billion yen, will be directly available to support research in national universities. Therefore, the estimated total Grants-in-Aid support for research in national universities in 2002 FY is 122.1 billion yen (90.1 billion plus 32 billion) (approximately 740 million USD) net of overhead deductions.

This 122.1 billion yen is 71.6% of the total 170.3 billion yen Grants-in-Aid budget for the 2002 fiscal year. Using this discount factor for FY 1998 gives an estimate of 84.5 billion yen (0.716 multiplied by 118 billion) (approximately 510 million USD) for the total amount of direct Grant-in-Aid research support to national universities in 1998.

Donations (Kifu-kin):

Data from METI³¹⁵ shows a 1998 total of 45 billion yen (approximately 270 million USD). METI confirmed these funds are for national universities only and there are no overhead deductions at the national government level. However, universities and individual departments have the option of taking deductions for common expenses/funds. The Author believes, largely on the basis of his experience in the University of Tokyo, that total deductions range between 5% and 10%. Applying an average discount of 7.5% to the above figure yields an estimate of 41.6 billion yen (approximately 250 million USD).

³¹⁵ Communication between METI and the Author (June 2001) (on file with author).

Commissioned Research:

Total Commissioned Research (government and private) in national universities in 1998 was about 38 billion yen (approximately 230 million USD).³¹⁶ Data from the University of Tokyo in 1999 shows that total Commissioned Research in 1999 in that university was 8.35 billion yen (approximately 50 million USD), of which 8.04 billion yen was from government-affiliated organizations and 310 million yen was from private companies. Assuming that the private company funds were all net of a 30% overhead deduction, but none of the government funds were subject to overhead, private companies paid 440 million yen for Commissioned Research in the University, in comparison to 8.04 billion yen paid by government affiliates. In other words, the private and government proportions were 94.8% and 5.2%, respectively. Assuming this ratio applies to the nationwide total of 38 billion yen and then discounting the private portion by the 30% overhead charge suggests that government funds directly available for Commissioned Research in national universities were about 36 billion yen (approximately 220 million USD), while directly available private funds were about 1.4 billion yen (approximately 8.5 million USD).

Joint Research:

Nationwide funding totals are not generally available. However, a personal communication from University of Tokyo officials (May 17, 2002) indicates that the 1998 total for national universities was 5.7 billion yen (approximately 35 million USD). University of Tokyo data indicate that Joint Research funding paid to the University of Tokyo that year totaled 678 million yen (approximately 4.1 million USD), 524 million yen (approximately 3.2 million USD) from private companies and 154 million yen (approximately 1 million USD) from government-affiliated organizations. Assuming that all the private-company funds were net of a 30% overhead deduction, but none of the government funds were subject to overhead charges, private companies paid 748 million yen (approximately 4.5 million USD) for Joint Research in the university, in comparison to 154 million yen paid by government affiliates. In other words, the private and government proportions were 82.8% and 17.2%, respectively. Assuming this ratio applies to the na-

³¹⁶ Data from METI (June 2001) (on file with author).

tionwide total of 5.7 billion yen and then discounting the private portion by the 30% overhead charge, private funds directly available for Joint Research in national universities were about 3.3 billion yen (approximately 20 million USD), while directly government funds were about 1.0 billion yen (approximately 6 million USD).

Unlike NSF data on R&D in U.S. universities, the above funding amounts/programs do not include funds for salaries or employee benefits (except for support staff hired primarily with Donations and small numbers of graduate students³¹⁷). Nor do they include funds for construction, maintenance, or infrastructure support with the following exceptions: (1) *Kou-hi* funds do pay for a portion of maintenance and nonconstruction infrastructure costs,³¹⁸ (2) 30% overhead is taken from Commissioned or Joint Research funds for the national higher education budget account, and (3) universities usually take 5 to 10% of Donation funds for common uses. Thus, the levels of R&D support listed in Table 1 should not be used to compare R&D support in Japanese universities with universities in other countries.

APPENDIX 3: MATERIAL TRANSFER AGREEMENTS (MTAs)

MTAs are agreements to transfer nonpatented or nonpatentable research projects from one institution to another, primarily for the purpose of research. Usually no royalties are involved. Standard provisions state that ownership remains with the transferor, that transferee will not use the material only for research not involving humans, that transferees will be liable for any damages involving its use of the material, and that transferees will acknowledge transferor's contribution in publications, etc. As U.S. academic institutions have asserted ownership over all work products of their employees, they have required that all transfers of research materials that do not occur under license occur under MTAs.

In the United States, MTAs have become controversial because they sometimes embody "reach through" clauses that require the transferee to transfer back to the transferor IP rights in any discoveries the transferee makes using the materials, or to give the transferor the right to take an exclusive license to such discoveries. Private companies often include such clauses when transferring

³¹⁷ See *supra* § 3.1.2.1.3.

³¹⁸ See METI data, *supra* note 173.

research materials to academic laboratories. Some academic laboratories include such clauses when transferring materials to companies or even other academic laboratories. Startup companies often include such clauses when transferring to companies or academic laboratories. The concern that such reach through clauses would limit the access of NIH-funded researchers to needed research materials (especially research materials produced with NIH funding) was one of the main reasons behind NIH's issuance of its 1999 Principles and Guidelines on Obtaining and Disseminating Biomedical Research Resources.³¹⁹ Thus in the United States, MTAs are not only a mechanism to transfer physical technology, but also serve as a mechanism for companies, and occasionally, even to academic institutions, to protect and extend their IP rights. One unintended consequence is that scientists often complain that MTAs have made the process of sending and receiving materials more time consuming and bureaucratic than in the past.

In contrast, Japanese universities, Riken, and some other GRIs have left ownership of nonpatented research products in the hands of inventors, although there has never been any notification or similar official ruling to this effect. Increasingly, some professors use a short MTA with standard clauses (not including reach through provisions) when they send research materials to other laboratories, but often no agreement is used. This practice makes sense in situations where universities do not have independent legal status and therefore cannot control nonpatented fruits of research. The only other possible locus of ownership would be the central government. Central government ownership, if accompanied by the need for central government bureaucrats to authorize or review transfers, would be a disaster.

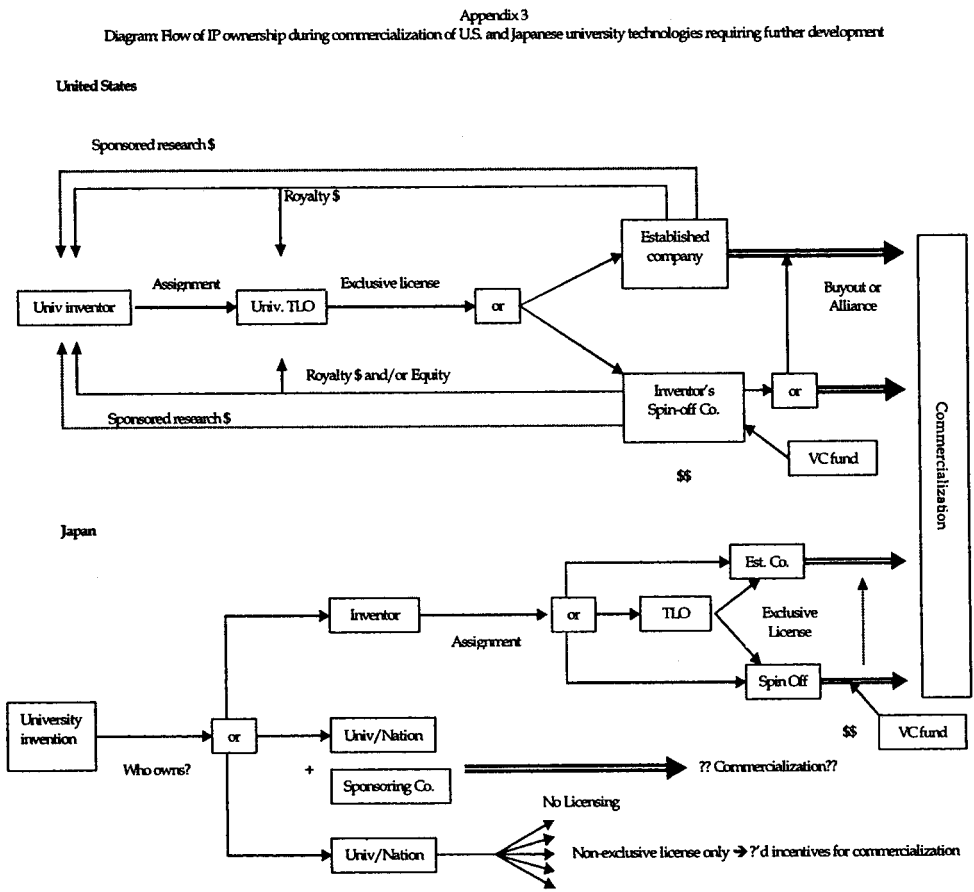
However, the indictment by the U.S. Justice Department in 2001 of two Japanese biomedical scientists for violating the Economic Espionage Act of 1996³²⁰ sparked interest in Japan regarding the MTAs and control rights over nonpatented and noncopyrighted fruits of academic research. The case involved a transfer by scientists of cell lines and reagents from the Cleveland Clinic, where he was an NIH-funded researcher, to Riken where he had obtained a new job. It was noted that the scientist may not have

³¹⁹ See *supra* note 39 (citing fears that universities issue too many exclusive licenses).

³²⁰ 18 U.S.C. §§ 1831-39 (1996).

known that the Cleveland Clinic owned the cell lines and reagents, and that in any case, he probably could have had them transferred to Riken under an MTA.³²¹

A number of proposals are now under discussion. Some would require reporting MTAs to either the sending institution or to MEXT. Others would require MTAs to be used in all transfers of research materials from the post-2004 University Corporations, and would also give these corporations the right to assert ownership over all nonpatentable research products.



321 Robert Kneller, Letter, "Espionage" Charge May be Based on a Misunderstanding of the Rules, 411 NATURE 991 (2001).