Current Issues of IP Management for Health and Agriculture in Japan

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ABSTRACT

This chapter describes current and historical trends and issues related to intellectual property (IP) management in Japan. It gives a history of Japan's national IP system in order to provide an understanding of the nature of the system and why and how it was established. The chapter also describes current government efforts to provide insights into the system's future. With regard to current IP issues, two topical issues are discussed: industry-university collaboration on R&D and employees' inventions. Japan's efforts to resolve these issues may be helpful for other countries that are grappling with similar issues.

The chapter also details health and agricultural IP issues in Japan. It discusses and compares with the practices of other countries the patentability of medical methods and exemptions for the experimental use of patented products. Furthermore, the chapter offers an overview of Japan's national policy on agricultural R&D and bioresource centers (the functioning of which greatly involves the transfer of materials with IP rights). RIKEN (The Institute of Physical and Chemical Research) is offered as a case study to clarify the policies and issues discussed.

Finally, for the benefit of other countries that are coming to terms with IP management issues, the chapter offers some lessons learned by Japan that have helped shape its national IP policy, strategy, and institutional IP management.

1. INTRODUCTION

Japan's recognition of the importance of IP—and the importance of good IP management to economic and scientific development—at one time lagged behind that of other developed countries. This was partly due to Japan's national isolation policy, in effect between 1603 and 1867, a time during which other advanced countries were beginning to establish their patent systems. Once international trade resumed in Japan, it established its own patent system, incorporating standards set by other countries and adapting them to domestic circumstances. Since the 1980s, Japan's national IP policy has changed significantly. Former Prime Minister Junichiro Koizumi's policy of "*Chitekizaisan-Rikkoku* (Nation Built on IP)" in 2002 reflected the country's new pro-patent policy. Since 2002, IP policy and a legal framework for IP rights protection have been reasonably well established for all categories of industrial invention.

In pursuing this recent national IP policy and strategy, however, issues have been raised by various stakeholders, involving industry–academia collaborative partnerships and the status of employees' inventions. To address the former, the Japanese government has made great efforts over the last decade to promote university–industry partnerships to effectively commercialize research results. In regard to employees' inventions, provisions in Japan's patent law were enacted rather early in its patent-legislation history. After several revisions, the current provisions came into effect in April 2005. Still, even after these revisions, several lawsuits by former employees claiming better remuneration from their

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employers for their inventions have raised significant debate.

Japan's status as a highly industrialized, developed country has been achieved partly through an IP rights protection system that, since 1975, has been harmonized with major international legal instruments,[1] including the World Intellectual Property Organization (WIPO). Japan participates in the following treaties associated with IP laws: the Paris Convention for the Protection of Industrial Property (1899 [years in parenthesis are those when Japan ratified/acceded to the convention or institution]); the Bern Convention for the Protection of Literary and Artistic Works (1899); the Universal Copyright Convention of 1952 under the United Nations Educational, Scientific, and Cultural Organization (UNESCO, 1956); the Patent Cooperation Treaty (PCT, 1978); and the Union for the Protection of New Varieties of Plants Convention (UPOV,1982). Japan has a branch office of AIPPI (Association Internationale pour la Protection de la Propriété Industrielle) (1956), called AIPPI-JAPAN.[2] The country is a member of the Convention on Biological Diversity (CBD, 1993), which emphasizes the importance of genetic resources, traditional knowledge, and access and benefit-sharing—including IP rights protection.

On the other hand, Japan has not signed the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA).[3] These abstentions are principally due to concerns about the protection of IP rights that may not synchronize with WIPO and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization (WTO). In the near future, when IP matters are better understood in domestic debates and corresponding laws are made, Japan may agree to actively participate in these major international treaties.

In addition, IP laws in Japan have peculiarities with regard to health and agriculture: 1) some aspects of medical technology, such as surgical operation methods, cannot be protected due to public equity concerns in IP laws (this is not the case in the United States); and 2) as in the majority of developing nations, traditional knowledge in agriculture is recognized as a public good.

2. JAPAN'S IP POLICY AND STRATEGY

Japan's IP policy and strategy developed from a relatively primitive level through the formation, addition, and revision of patent laws since the Meiji era (1868–1912), when Japan abandoned its policy of national isolation after the Edo era (1603–1867). For more than 200 years (1616–1854), the government had banned foreign contact, except for very limited contact with only a few countries.[4] Japan refused to import or utilize advanced technologies developed in the United States and Europe. After reopening the country to trade in 1858, however, Japan began to work to catch up with industrially advanced countries by introducing invention-promotion systems and a national patent system.

During the last five years, in addition to developing patent laws, the government has promoted its national IP policy and strategy by developing general national frameworks and establishing a special function in the Cabinet. All of this was initiated by former Prime Minister Koizumi.

2.1 *History of Japanese patent law*

In 1624, England adopted a patent ordinance that is the basis for today's British patent system. The adoption of this first patent ordinance was followed by the adoption of patent legislation in the United States in 1790, and in France in 1791.[5] During this period (the Edo era), Japan pursued a policy of national isolation, and the manufacturing of new products based on technologies developed in European countries and in the United States was prohibited. In the 1870s, the Meiji government sought to establish the Japan's first patent law.[6]

In 1871, the first patent law — known as the Exclusive Right Law—was passed and enacted. The government, however, was not prepared to implement such a law: there was no government office to accept patent applications and no officials to handle them. Furthermore, the public were generally against proprietary inventions, and so the new patent system was not widely accepted. Ultimately useless, the law was abolished one year after it was passed. Without a patent law, imitations and misappropriations of inventions were widespread, and inventors frequently

lost profits from royalties. In 1885, a new patent law was passed that followed the U.S. and French patent laws. Having learned from the failure of the Exclusive Right Law, the government established a patent bureau in the Agriculture and Commerce Ministry and staffed it with a director, three judges, an examiner, and an assistant examiner. By 1899, the bureau had expanded to five judges, 15 examiners, and 20 assistant examiners; and the number of patent applications was doubled in 1887, reaching 1,515 in 1899.[7] The patent ordinance, however, was still imperfect and far from its modern version.

Since 1887, Japan's patent system and law have been revised many times, mainly because of pressure from domestic proponents and developed countries. The modernization of the patent law began in 1921 through a revision that aimed to accommodate the increased demand for Japanese products as substitutes for foreign products during World War I (international trade had been suspended and high-quality foreign technologies and materials could not reach Japan during those years [1914–1918]). After World War II (1945–1949), Japan's principal economic objective was "*quantitative recovery, ignoring efficiency.*" This changed only after the 1950s, when economic control and subsidies were gradually abolished, the market mechanism was largely restored, private international trade began, political independence was regained under the San Francisco Peace Treaty (1951), and U.S. economic assistance to Japan ended.[8]

Japanese industry began to pursue efficiency and competitiveness, which required cost reductions and higher-quality products. Moreover, "*it was a time when the number of patent applications resulting from active industrial investment in research and development was increasing, causing a variety of problems to emerge, such as late examination, etc.*"[9] Despite these circumstances, the patent law remained unchanged until 1959. The revision in 1959 was intended to cope with the needs of a newly liberalized economy and developments within international patent systems. More revisions followed in 1970, when technological development had become increasingly rapid and industrial property issues were extremely significant for Japan.

Japan's rapid economic growth stalled in the early 1970s, demonstrating that Japan had caught up with developed countries and had matured economically and industrially. At such a point in a modern economy's development, the economy can no longer grow through imitation but must innovate to spur growth. Japan's revision of patent law in 1975 aimed not only at the creation of new technologies but also at international harmonization. The revision included a substance-patent system and a multiclaim-application process.

As international harmonization proceeded in the 1980s and 1990s, various kinds of new institutions for pro-patent policies were introduced. The most influential factor was pressure from advanced countries represented by the United States, which feared the incremental rise of Japan's export market and strongly promoted a domestic pro-patent policy during that period. Local voices called for the strengthening of Japan's patent system to further development and prevent an increasing risk of the country's original technologies and products being copied abroad, especially by developing countries, such as China, that were trying to catch up with developed countries.[10] Japan's pro-patent policy has expanded the scope of patent protection, extended the patent period for pharmaceutical products, and strengthened deterrence against infringement.

In 1990, the Japan Patent Office (JPO) was the first patent office in the world to start a paperless system to accept and handle patent applications.

2.2 *Recent IP policy and strategy*

Having recognized its need for more creative and advanced technological innovations, Japan has emphasized a pro-patent policy since the early 1990s. In line with this position, former Prime Minister Junichiro Koizumi's policy statement in February 2002, proclaiming that he would make Japan a country built on IP, followed the passage in 1998 of a "law on promoting technology transfer from universities to industry," so-called "TLO Law," and the Japanese version of the Bayh-

Dole Act (Article 30 of the 1999 Law of Special Measures for Industrial Revitalization).[11]

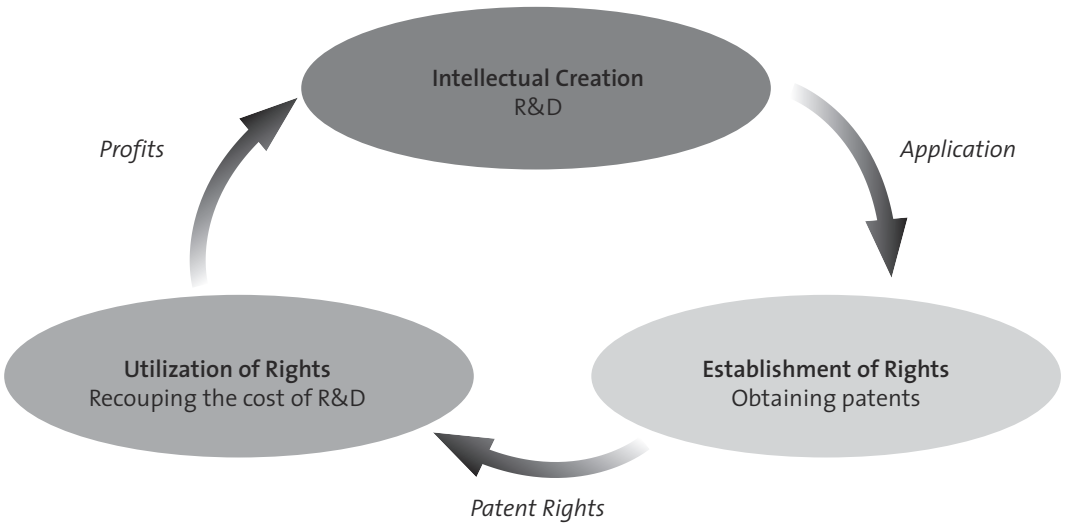
During its period of high economic growth, Japan had been good at exporting technologies based on imported technologies. After reaching the global technological frontier, however, Japan's advantage came under attack, especially by neighboring countries, such as China, that had plentiful, cheap labor and increasing technical and economical power. Japan suffered from an economic recession in the 1990s and created a plan to break the impasse of the recession. The *Chitekizaisan-Rikkoku* plan would add value to the technologies, products, and culture created in Japan for export overseas by further strengthening the nation's IP regime and management. This entailed specific, concrete provisions for planning and policy implementation.

Having been regarded as fundamental for national development, the former patent system had been established largely to stimulate domestic industries. Under the *Chitekizaisan-Rikkoku* plan, Japan began to make more substantial efforts to develop and implement an IP strategy, focusing on IP rights generated not only from the private sector but also the public/university sector.

In March 2002, one month after the government's policy statement, the prime minister's cabinet inaugurated the Strategic Council on Intellectual Property, which discussed the details of the plan. The Council created an Intellectual Property Policy Outline in July 2002.[12] It referred to an "*intellectual creation cycle*": the cycle of the creation, protection/establishment, and exploitation/utilization of IP/IP rights (Figure 1). Aligned with other global IP systems, the cycle established a mechanism to create high-quality IP protected by patents. Protected IP is exploited throughout society, and the resulting profits are used to recoup the cost of original R&D and to invest in the creation of new IP. The cycle is considered fundamental to the government's intellectual property policy outline and to Japan's recent IP strategy.

Furthermore, the December 2002 Basic Law on Intellectual Property[14] was promulgated in pursuit of implementing the IP strategy and

Figure 1: Intellectual Creation Cycle



Source: METI[13]

stipulated the establishment of the Intellectual Property Policy Headquarters (established March 2003 in the cabinet). In July 2003, at the fifth meeting of the Intellectual Property Policy Headquarters, a promotion program (called the "Program for Promoting the Creation, Protection, and Exploitation of Intellectual Properties"[15]) was initiated. This program set out specific goals and time frames for implementing the new IP strategy. The program has been implemented and reported upon annually since then as the "Intellectual Property Strategic Program."[16] The reports are composed of five sections: Creation (of IP), Protection (of IP), Exploitation (of IP), Expansion of Content Business, and Developing Human Resources and Improving Public Awareness.

3. INDUSTRY–UNIVERSITY COLLABORATION OF R&D

Japanese central and local governments have promoted partnerships among industry, academia, and government—particularly between industry and academia. Industry provides information on public or market needs; academia provides the seeds for commercializing technology (that is, inventions); and the government plays the role of agent or mediator between industry and academia.

Measured in terms of publications and in acquiring publicly available competitive grants, national universities have been the leading academic institutions in basic research. Out of more than 500 universities registered by the Ministry of Education, Culture, Sports, Science, and Technology (MEXT), the top 20 universities acquiring extramural funding are national universities involved in all fields of research. In the medical, pharmaceutical, and physical sciences, certain private universities have an advantage over others due to specialization, but national universities generally lead. National universities have also been more engaged in collaborations with industry for some time. In 2004, 92.2% of national universities had established an office for cooperation with industry, such as a technology transfer office (TTO) or a technology licensing office (TLO); this compares to only 42.8% of private universities and 59.6% of national research institutes.[17] However, the effectiveness of such collaboration has been hindered due to unclear R&D policies with industry, poor IP controls, lack of incentives for researchers at universities, legal constraints stemming from the nature of national universities, and general administrative slowness.

At leading private universities, implementing industry–university collaborations has been much easier due to the relative ease of contractual negotiations, administrative procedures, and the lack of restrictions on the dissemination and use of funds. Still, only a limited number of private universities have been able to accommodate very active collaborations.

3.1 *Reforming national universities*

In 2004, all national universities were separated from the direct supervision of MEXT and became independently managed administrative institutions. Currently 89 national universities and four educational research institutions have reformed. The numbers will be further reduced by mergers and acquisitions. The key aspects of increased independence are: (1) all decision making can be made by each university's administration and council instead of requiring approval from MEXT; (2) a medium-term plan for each six years is used as an achievement evaluation point; (3) funding is granted by MEXT based on the medium-term plan; (4) profit acquiring and commercial activities are permitted; (5) academic faculty members have more flexibility in creating business ventures; (6) TTO and IP controls are enforced at each institution, with the resulting expectation that university–industry collaboration will be boosted; and (7) faculty members are provided incentives to innovate. Despite all this, the overall system still needs to be revised, and governance needs to be improved to enhance the implementation of R&D and technology transfer from academic institutions.

With the reform of the national universities, the government now increasingly promotes academic institutions to enhance industry–academic institution collaborations and to establish TTOs.

The development of small business ventures by faculty members has also been encouraged in order to commercialize their research. According to the Intellectual Property Strategic Program 2005, the number of new venture companies derived from universities was 199 in fiscal year 2003, and 129 in fiscal year 2004, for a total of 1,112 by the end of fiscal year 2004. Universities provide support grants for such business attempts, but often overall strategic plans are missing on the university side. Insufficient consideration is given to IP rights, which are a strong driving force toward venture-business success. Each university has taken its own approach to alleviating these weaknesses.

3.2 *Technology/IP rights transfer between universities and the private sector*

Under Japan's former national academic institution system, it had been difficult to exploit IP rights because: (1) IP rights, particularly patents, were owned by the Japanese government; and (2) many academic institutions lacked the systematic capacity to form university–industry liaisons. The old national university system deterred the promotion of invention and proper legal handling. Additionally, it seems that universities did not give scholars much incentive to innovate and invent. Faculty members also often would abandon patent applications due to high costs and the university's propensity for rejecting patent applications. Instead, faculty members often allowed ownership rights to be transferred to the private sector in return for gift donations for their research. This in turn hindered the development of research and business opportunities from universities. A survey of the top-ten major national universities in terms of extramural research-grant acquisition, revealed that legal and administrative systems often lagged far behind the private sector's ability to facilitate collaboration or complex contractual matters.

Due to changes in the law, however, the past ten years have seen robust growth in the establishment of TTOs at universities. University IP offices take care of governance issues, and TTOs support the technology transfer process. In general, university TTOs have four functions: (1) IP rights protection, (2) marketing of university-derived technologies, (3) licensing, and (4) promotion of commercial ventures by faculty members. TTOs have been legally supported by the government since 1998. The TTOs that have been approved by MEXT and the Ministry of Economic, Trade, and Industry (METI), "approved" TLOs are entitled to special treatment under the TLO Law and the "Japanese Bayh-Dole" Law. The treatment could include direct funding by ministries and free or discounted fees for the maintenance of patent rights and examination requests. Between 1998 and April 2006, 41 such TLOs were established. In addition, there were four "accredited" TLOs as of April 2006. These TLOs are assigned nationally owned patents and then out-license them, while the approved TLOs register patents for university faculty—and exploit their inventions. Guidelines and reports for these TTOs have been published.[18] (A detailed list of approved and accredited TLOs is available upon request from the authors and from the METI JPO Web site.[19])

Japanese universities are recognizing the importance of their own IP for commercializing research and establishing technology-based companies. There are an increasing number of university-derived companies (generally referred to as spinouts), particularly in the area of biotechnology, compared with five years ago.[20]

3.3 *Human resource needs*

Generally, the key IP issue at academic institutions is processing ability. Establishing a contract on applied R&D takes time and requires specialists on legal matters. Universities are short of practical lawyers and officers, and it is common for most of the officers to be transferred to a different section of the university within two or three years, which prevents these individuals from gaining sufficient skills and knowledge.[21] This hinders efforts to implement and disseminate research results and applications promptly and smoothly. Japanese universities are in great need of institutional reform related to the administration of contractual matters and industry–university collaborations.

While the number of patent attorneys who specialize in various disciplines of modern tech-

nologies in Japan has dramatically increased, an overall understanding of the IP management by patent attorneys is crucial. Patent attorneys may have specific know-how related to recent changes in the patent law, but joint activities with lawyers are often required to identify or challenge infringements of IP rights. With regard to the commercial aspects of IP management, much needed are multiskilled specialists who are competent in both the legal and technical aspects of technology transfer in marketing, licensing, and integration of IP rights.

The Intellectual Property Strategic Programs emphasize using university infrastructure to develop IP specialists. Such individuals are not only needed to manage IP in universities but also in the wider business market. Multidisciplinary graduate school programs are increasingly being offered at many universities, but professionals with such know-how are still few, so TTOs often offer seminars/workshops on IP education and practical operations for their faculty members and senior graduate students. Through these efforts, IP courses are becoming popular at many universities.

4. EMPLOYEES' INVENTIONS

Information surveys, such as those published by the Mitsubishi Research Institute,[22] point to Japan's lack of strong incentives for researchers and engineers as a potential pitfall. The problem is caused by the weak support for employees' inventions created through the work service. Article 35 of Japan's patent law defines employees' inventions, but the law is often criticized for not promoting employees based on their record of inventions and formal IP, especially at public institutions. Compared to the United States, where public institutions file for many patents, relatively few patents are filed by Japan's public institutions. This is true especially for the national universities. Instead, Japanese academia recognizes and rewards publishing, which is used as almost the sole criterion for promotion.[23] MEXT and its subsidiary organization, JSPS (Japan Society for the Promotion of Science), have noted the low number of patent filings at academic institutions and have used grants to encourage promotions based on the patenting of inventions.[24] Over the last few years, patent filing and registration have drastically increased under the Research for the Future Program promoted by MEXT and JSPS.[25]

The debate between employers and employees about their proportional ownership of inventions at universities dates back to the 1970s.[26] After some argument, MEXT reported in 2002 that inventions created by faculty at universities should be owned by universities. This principle has since been the basis of university IP management strategies. Meanwhile, according to a survey conducted in 1997 by the Japan Institute of Invention and Innovation (JIII),[27] more private companies have been providing relevant regulations and rules and have been increasing remuneration and employee incentives to generate inventions. The survey revealed that:

1. An increasing number of companies have regulations and rules established.
2. Remuneration is made at different milestones, such as patent application, patent registration, and exploitation/working. The proportion of companies adopting such remuneration rules has increased for all the milestones.
3. The amount of remuneration is fixed for some companies; others value it in proportion to the profit acquired from the invention.
4. In both cases, the average amount of remuneration generally has increased.

The recognition and awareness of employees' inventions and their remuneration have been rising for the last decade; nevertheless, various issues remain.

4.1 *Laws on employees' inventions*

The Patent Law of 1909 gave the patent right to an employee invention to his or her employer, but ownership reverted to the employee under the 1921 Patent Law. The 1921 law aimed to protect employees by ensuring that they received reasonable remuneration when the right of ownership was passed to the employer (in accordance with

contracts made in advance).[28] The Patent Law of 1959, Article 35, revisited these provisions governing employees' inventions. The law declared that if an employee's patented invention was classified as an *"employee's invention"* (as defined in the patent law[29]), the employer had the right to a nonexclusive license. The same law stipulated that the employee is entitled to reasonable remuneration if he or she assigns the patent right, or an exclusive right to such invention, to the employer in accordance with contracts, regulations, and other stipulations. The law also provided that the remuneration amounts would be decided by referring to the profits that the employer would make from the invention and to the amount of the employer's contribution to the invention.

4.2 *New policy and strategy on employees' inventions*

As mentioned earlier, the Intellectual Property Strategic Program 2003 was adopted in July 2003. The Creation part of the program states the following provision to employees' inventions:

Abolishing or Amending the Provision Regarding Employees' Inventions under the Patent Law.

For the purpose of securing R&D incentive for inventors, reducing patent management cost and risk in individual companies, and strengthening the industrial competitiveness of Japanese industry, the GOJ (Government of Japan) will consider necessary issues on an employee's invention, while taking into account the changes in the social environment, and submit a bill to abolish or amend the provision in Article 35 of the Patent Law to the ordinary session of the Diet in 2004.

Consequently, in December 2003, a METI committee of professionals from universities and from the public and private sectors, with expertise in law and in science and technology, created a report titled "What employees' inventions should be."[30] The report suggested amending the provision regarding employees' inventions instead of abolishing it. The National Forum for Intellectual Property Strategy appeared at the same time. With a range of expertise including lawyers/patent attorneys, research scientists, business executives, and journalists, members of the forum asserted that the provision should be abolished. The details of the various views are discussed below. Based on the METI committee's report, the amendment of Article 35 of the patent law went into effect in April 2005.[31]

4.3 *Amendment of Article 35*

An employee's invention is defined in the law as an invention "*which by reason of its nature falls within the scope of the business of the employer, etc. and an act or acts resulting in the invention were part of the present or past duties of the employee, etc. performed on behalf of the employer, etc. (Article 35.1).*" In other words, an employee's invention results from R&D conducted by an employee as part of his or her work within the scope of the employer's business. There are two other types of inventions mentioned in the law: those created by an employee, but outside of his or her work service, and those created by an employee outside of the employer's scope of business. These differences in the three types are explained in the provisions. Although the employee's invention is created by the employee's own efforts and abilities, the employer contributed to the creation by providing salary, facilities, equipment, and expenses. Considering such contributions, the law provides that the employer shall have a nonexclusive license on the patent right in order to gain appropriate remuneration (Article 35.1).

Article 35.2 stipulates that, provided the invention is the employee's invention, the contractual provision, service regulation, or other stipulation made in advance shall be valid, and the employer shall be given the right to the patent or to the exclusive license. This provision is said to protect employees from being exploited if inventions fall outside of the scope of the employee's invention. The employee shall have the right to reasonable remuneration when he or she has transferred the right to the employer in accordance with the contract, service regulations, or other stipulations (Article 35.3).

Although there has been no amendment for Article 35.1 to 35.3 since the 1959 Patent Law, the subsequent two sub-clauses, Article 35.4 and 35.5, were amended. As mentioned above,

Article 35.4 of the 1959 Patent Law stipulated that the amount of the remuneration shall be decided by referring to the profits that the employer will make from the invention and to the employer's contributions to making the invention. The new Patent Law of 2005 stipulates that when the contractual provision, service regulation, or other stipulation between the employer and employee determines the criteria for remuneration, the criteria should be reasonable. Reasonableness shall be determined by considering the decision process of the criteria, such as the conditions of discussion between the employer and employee, hearing of the employees' views on the calculation, and the disclosure status of the criteria.

If judged as unreasonable in accordance with Article 35.4, the amount of remuneration shall be decided in light of the profit, expenses, and other contributions of the employer regarding the invention, the treatment of the employee, and other circumstances (Article 35.5).

4.4 *Current issues regarding employee's inventions*

In the last few years, the increasing number of employees who have resigned from their companies have been suing their former employers due to dissatisfaction with the remuneration paid for inventions the employees created during their employment. The surge in the number of lawsuits reflects an increasing awareness of IP among employees and has aroused the public's interest in IP and employees' inventions. The most famous case, known for the exceptional amount claimed by the employee, is the lawsuit between Dr. Shuji Nakamura and his former employer, Nichia Corp., Ltd., a chemical maker, concerning his invention of a blue light-emitting diode (LED). Originally claiming 20 billion JPY, the court decided Dr. Nakamura was entitled to receive about 600 million JPY (plus interest payments of about 240 million JPY) from his former employer. The case had been reviewed by the Tokyo District Court (2004) and the Tokyo High Court (2005) before it was settled in 2005. It is noteworthy that there was an enormous difference between the percentages that the two courts identified as Dr. Nakamura's contribution: 50% in the district court and 5% in the high court. Dr. Nakamura certainly lost a large amount, but generally the case is considered to be a victory for the employee.

Over the last few years, other former employees have gained more than their former employers had expected to pay. The Japan Intellectual Property Association (JIPA)[32] cautions against extreme legal moves to support remunerations for employees' inventions because overestimated valuation of inventions may destroy some employer companies. The purpose of Article 35 is primarily to appropriately balance the interests of employers and employees. Both the employer and employee require significant—and often different—incentives to ensure that appropriate, relevant investments are made to enable and stimulate innovation.

History suggests that the provisions for employees' inventions under the patent law have been ineffective. Some groups, such as the National Forum of Intellectual Property Strategy, and some private companies fearing huge employee remuneration costs have argued that Article 35 should be abolished or, at least, amended.[33] The critics contend that the individual contractual provision, service regulation, and other stipulations made in advance between the employer and employee (or individual agreements) should be considered reasonable unless they were made under conditions of fraud, duress, or other unreasonable processes.[34] Individual agreements, not Article 35 *per se*, should be applied to settle disputes between the employer and employee regarding the employee's invention.

The same critics argue that the following issues regarding employee's invention under the current Patent Law (Article 35) are also important:

- Criteria for calculating the amount of remuneration have varied from court to court and from case to case. Without any rigid criteria, the decision is vulnerable to the subjective calculations of the judge (as seen in the Nakamura case)
- Criteria for judgment of an "unreasonable" payment in accordance with Article 35.4 are obscure

- Ultimately, it is dubious whether or not a court has the ability and capacity to judge the reasonableness and appropriateness of the remuneration amount

5. HEALTH-RELATED ISSUES

5.1 *Patent protection on methods for medical activities or practices*

5.1.1 *Patentability and unpatentability*

In Japan, medical methods are out of the scope of patentability; however, pharmaceutical products and medical equipment products are patentable. This is inconsistent with U.S. and E.U. practices. In the United States, methods relating to medical activities and practices are generally patentable. Under 35 U.S.C. 287 (c)(1),[35] however, a medical practitioner can use patented medical methods without risking infringement. In the European Union, under the European Patent Convention (EPC), Article 52 (Patentable inventions)[36] stipulates that methods to treat the human as well as animal body by surgery or therapy, as well as diagnostic methods practiced on the body, shall not be regarded as inventions that can be applied industrially. In other words, the methods of operation, treatment, and diagnosis of the human body are not protected by patent rights. However, as an exception to that rule, the first two of the three stages in diagnostic methods: data collection, their comparison, and decision making of medical treatment, have been interpreted as patentable according to the EPC.[37]

In Japan, first and most fundamentally, medical methods fall out of the scope of patentability according to patent law Article 29 (1).[38] In other words, they are regarded as inventions that are *not* industrially applicable because of their humanitarian implications in the medical field. It was feared that patients' wellbeing might be jeopardized by patent protection, which could have effectively deterred medical practitioners from utilizing certain methods if they did not have a license from the patent owner. Secondly, medical activities including R&D are generally regarded as being not for profit, and it is widely held that incentives should be based on academic appraisal and rewards rather than economic gain. Additionally, innovation in the medical field was largely conducted by universities and public institutions that were sufficiently funded by the public sector, which eliminates the need to rely on the modern, private model of patenting and receiving royalty earnings from licensing.[39] Consequently, the decision was made that medical methods should be excluded from patent protection.

However, many players in both academia and industry regard this decision as outdated because of various changes that have taken place in Japan over the last decade.

5.1.2 *Trends in perspective*

The most prominent issue relating to the nonpatentability of medical methods is the lack of incentives for pursuing costly, risky innovation in the medical field. In addition to the major roles of universities and public research institutions in medical innovation, bioventures (biotechnology ventures) and spinouts have increased their role over the last decade because of the increased recognition of IP rights and the establishment of TTOs in universities and public research institutions. Needless to say, such privately run companies cannot expect public funds to cover the costs of this increasing investment, much of which is directed at the universities and public institutions. Instead, it is increasingly expected that investment costs will be covered by patenting and licensing. However, companies have no way to generate returns on investments into medical method inventions. Moreover, their inventions can be easily copied and utilized freely by others. Not surprisingly, therefore, potential bioventure companies are not eager to enter the field.[40] In the absence of actively nurturing this sector, many believe that Japan's competitiveness in this field will weaken because investments in medical innovation will always be deterred. In the long run, patients may lack access to new, highly effective diagnosis or treatment methods that could be developed locally. There may also be negative economic consequences.

Some critics argue that excluding methods and processes from patent protection does not

comply with the TRIPS Agreement, which stipulates that patents shall be available for all inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step, and are capable of industrial application (Article 27).[41]

Thus, it is increasingly felt that not just medical products, but also methods, should be considered inventions with industrial application that should be given patent protection.

Based on the above analyses, the government of Japan is reconsidering patent protection for medical methods. In response to recent changes in circumstances and views, the government established a task force on "*the protection of patents of medical-related acts.*" The task force committee was established under the Intellectual Property Policy Headquarters and began consultations in October 2003.

The main purpose of the meetings was to discuss whether or not medical methods should be covered by patent protection. The committee published a summary report of their discussions in November 2004,[42] which involved hearings from not only committee members but also other professionals from various fields, such as medical science, the medical industry, medical economists, and the legal field. The report also included public comment. After 11 meetings, the summary report made the following recommendations:

- From a humanitarian standpoint, the methods relating to medical activities by medical practitioners should be excluded from patent protection.
- Operational methods of medical equipment should be covered under the scope of patent protection, with the exception of those related to medical activities by medical practitioners.
- With regard to methods for generating new potent and efficacious medicines for production and sale, the possibility of expanding patent protection should be pursued by allowing product patents rather than process patents to begin with. Process patents could be discussed and pursued later on. The limited protection reflects the potentially obscure distinction between medical activities by medical practitioners and others.

In April 2005, based on the committee's recommendations, the government amended the practical examination criteria of medical inventions for patents and utility models.[43] The amendment makes explicit provisions for patenting methods and processes related to the use of medical equipment, but methods and processes related to medical activities by medical practitioners are not patentable.[44]

5.1.3 *Issues for the near future*

Although the examination criteria have been amended, some issues and arguments still require resolution. The report recognizes that medical methods for patients who need access to state-of-the-art medical practices should be excluded from patent protection. However, no such law has yet been passed, and legal guidance similar to the U.S. provision in 35 U.S.C. 287 (c)(1) is urgently needed.

Despite the report's conclusion, expanding the scope of process patents in the medical field to cover whole methods is still widely debated. Some argue that amending the examination criteria is insufficient and that Japan's competitiveness in the medical field will not be enhanced without protecting medical process inventions.

5.2 *Limitations of the patent right*

The limitation of the patent right or the exemption from patent infringement for the experimental use of a patented invention affects all fields in science and technology. Given its impact on public health outcomes, however, this limitation is important especially for biotechnological and medical experimentation.

5.2.1 *Background*

Article 69 (1) of the Japanese patent law provides that "*the effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research* (Limits of Patent Right)." The original purpose for establishing the patent law was "*to encourage inventions by promoting their protection and utilization so as to contribute to the*

development of industry (Article 1)," and extending the patent right to experimentation and research is considered contrary to this purpose. Such limitations to the patent right were originally inserted into the patent law of 1909, which was reaffirmed in Article 69 (1) of the patent law of 1959. Article 68 of the patent law also provides that a patentee shall have an exclusive right to "*commercially*" work the patented invention. The word *commercially* leads some to conclude that experiments and research conducted in universities and public research institutions will be excluded from patent protection because they are largely considered as nonprofit.

The patent law, however, does not clearly distinguish between profit and nonprofit purposes in terms of the effects and limits of the patent right. The above interpretation has depended solely upon legal theory, and very few judicial precedents have emerged regarding the interpretation of "*experiment or research*" provided for in Article 69 (1). Therefore, failing to obtain a proper license for utilizing a patented invention in experiments and research in universities and public research institutions can potentially be considered as infringement. Moreover, patent owners have a clear right to require universities and research institutions to obtain licenses for each invention used in their experiment or research. These procedural requirements and the related royalty payments deter researchers. If patent protection extends to experimentation and research linked to technological advancement, it could eventually thwart the evolution of national industry.

5.2.2 *The current situation and precedents*

The accelerated progress of biotechnology, the increased collaboration between academia and industry, and the enhanced awareness of IP strategy among various players over the last decade have heightened concerns over obscurity in the patent law. In the Intellectual Property Strategic Program 2003, the government decided to review and clarify the extent to which experiments or research are exempted from patent infringement. This review would investigate current situations and precedents not only in Japan but elsewhere, and the results would be widely disseminated to both the public and private sectors in order to reduce the possibility of conflict. Composed of experts and leaders from various areas, including executives of private companies, patent attorneys, faculties of universities, and representatives of TTOs, a working group on patent strategy established under the METI in 2003 discussed the issue in a report on issues relating to effective use of patented invention.[45] Completed in November 2004, the report focused principally on three aspects: the experiment or research, generally, clinical trials for approval of generic medicines, and experimentation and research in universities and public research institutions.

According to the report, very few judicial precedents in Japan interpret experiment or research, so guidance has been sought in legal theory instead of judicial rulings. The most widely accepted theory was described by Keiko Someno in 1988.[46] It limits experiment or research to the purpose of *"progress in technology,"* such as the examination of an invention's patentability, the examination of an invention's function, and experiments to improve or develop the invention.

The results of the investigation of other countries are summarized in Box 1 (see end of chapter). While the wording and scope vary from country to country, on the whole the laws provide an exemption from patent infringement for experimental use. In some countries, however, the interpretation of the provision is incoherent due to a lack of case history—and even the theories are variable in such countries. Still, in most of the countries, clinical trials to obtain regulatory approval are exempted, while there is no or very little case history regarding experimental use in universities.

The report concluded that Someno's theory is appropriate for Japan and in line with the situation and precedents of other countries. The report recommended its use to clarify the scope of the experiment and research exempted from the patent infringement. According to the theory (and given the fact that Japanese patent law does not distinguish between for-profit private companies and nonprofit universities and public research institutions when it comes to experiment or re-

search using a patented invention for the effects of patent right), experimentation and research conducted in universities and public research institutions are potentially infringement unless licenses are obtained from the patent owner. If the subject of the experiment or research is a patented invention itself and the purpose is technological progress, however, utilization is exempted from the license requirement. Likewise, Article 69 (1) is not likely to apply to the utilization of research tools unless the subject of the research is the patented invention itself and its purpose is for technological progress.

There have only been a few occasions when universities and public research institutions utilizing a patented invention for their experiment or research have been sued by private companies owning the patent right in Japan. However, the report notes an increased concern about such lawsuits, particularly because universities are more likely to create profits from experimentation and research using patented products through increased collaboration with private industry than in the past. Besides, the report emphasizes the importance of disseminating information and generating a consensus on this issue in both the public and private sectors in order to minimize the number of such conflicts.

6. AGRICULTURAL BIOTECHNOLOGY

6.1 *National policy on R&D*

Japan has pursued R&D in agricultural biotechnology in the public and private sectors since the 1980s, with the government and relevant public-funding supports determining priorities. While basic R&D has contributed to global plant biotechnology communities, Japan has not taken the leadership in the business development of agri-biotechnology.[48] Furthermore, even though academic publications are recognized within global R&D networks, Japan's national policy lacks a strategic vision in the area of technology commercialization.

Despite the huge investment made by the public and private sectors between 1980 and 1999, no fruitful commercialization has taken place in Japan,[49] except for small cases relating to transgenic flowers. Many factors have been suggested for this: the weakness of decision making by the public sector's senior administration—and the private sector's correlating impatience; an overall shortage of adequate human resources; the lack of a strategic approach to commercialization; disorganized IP strategies; poor accountability, particularly in public-funded research; poor public communication approaches and consequent negative sentiment; and unfavorable regulations for R&D, despite government policies to support overall biotechnology.[50] Compared with other biotechnology areas, no major venture capitalists or investment banks are actively funding Japanese plant biotechnology R&D.[51] On the other hand, investors need patience. In general, agri-biotechnology R&D is a slow process, which is reflected in the slow growth of related industry.

On the upside, policy related to general support for biotechnology as a national priority has been reformed by the Council for Science and Technology Policy (CSTP)[52] under the cabinet office. Under supervision from METI, government funding agencies, such as the Research Institute of Innovative Technology for the Earth (RITE),[53] the New Energy and Industrial Technology Development Organization (NEDO)[54] and the Ministry of Agriculture, Forestry, and Fisheries (MAFF), have refocused research on crop-genome and crop-biotech applications, while MEXT and JSPS continue to fund basic research. This may drive policy toward the developmental outcomes of the Kyoto Protocol on environmental biotechnology applications (including transgenic applications). In the long term, these developments could revive overall agricultural biotechnology, including genetically modified (GM) crops. Also, as is the case in the United States and Europe,[55] the private sector in plant biotechnology could restructure by redefining and limiting its business context and partners.

6.2 *Agri-biotechnology industry and IP rights*

The Japanese biotechnology industry is very large in terms of assets and investments and is growing rapidly. Biotechnology research in Japan covers a wide range of areas from the elucidation of

biological mechanisms to the development of new functional materials. Due to the broad spectrum of biotechnology, however, it is becoming increasingly difficult for a private company to monopolize, or even to know about, all the patents in a single product. Without intending to do so, a company can use another's patented technology inappropriately. The possibility of such patent infringement reaching the courts is increasing, and a complicating factor is the variety of national and international laws. In the field of agri-biotechnology, for instance, for new plant varieties it is unclear how laws/treaties on patent and those on plant variety protection should coexist or be applied.[56]

The number of ventures and spinouts in the area of biotechnology has increased, particularly since the reform of national universities into independently managed administrative institutions. Nevertheless, investors see agri-biotech companies as a high risk; their long-term efforts and contribution have been stagnant.[57] Major venture capitalists or investment banks are less likely to fund Japanese plant biotechnology R&D in comparison to other areas. Japanese companies have lost opportunities as a result, and key patents on plant biotechnology have been swept away by U.S. and European private companies, which strongly and adversely affected Japan's agricultural biotechnology industry. Numerous obstacles have contributed to this situation: (1) the complication of patenting inspection; (2) the tendency to grant wider coverage of patentable subjects, such as DNA sequences; (3) the changes in laws regarding patentable "process"; and (4) slow follow-up on litigation in agri-biotech IP rights.[58]

6.3 *Bioresources centers/genebanks*

Genetic resources have been well recognized as a key resource for R&D in Japan. To ensure synergy among germplasm banks, a consortium has been established that includes individual academic agencies. Similar to GRIN (Germplasm Resources Information Network)[59] in the United States, this information system is being further elaborated. There is common understanding of the uses of the germplasm acquisition agreement (GAA) and materials transfer agreement (MTA) from public bioresources centers/genebanks to different stakeholders in Japan. Details within MTA documents vary because each academic agency has to determine its own policies and rules under the common government framework.

The private sector also establishes its own MTA documents. These are based on different cases of use, such as basic research collaboration, R&D toward commercial orientation, collaboration with other private companies, and so forth. Although largely confidential, surveys made by the Japan Bioindustry Association (JBA) clearly reveal a system designed to accommodate various scenarios, particularly in relation to microorganisms. Plant genetic resources, however, are different, and Japanese seed companies still need to comprehend and tackle access and benefit-sharing issues under international debate—including the CBD and Treaty.

Case examples of access and benefit sharing (ABS) with southeast Asian countries emphasizing industrial applications include Indonesia with some pharmaceutical companies, Pathein University in Myanmar with the National Institute of Technology and Evaluation (NITE)[60] bioresources center, and the Forest Research Institute of Malaysia (FRIM) with Nimura Genetic Solutions (NGS),[61] a biotech venture-ABS company.

With the efforts of such intersectoral liaisons as JBA, some progress has been made in promoting and developing models for ABS-based R&D. However, Japanese academic institutions will be better able to address this matter by paying more attention to contemporary international discussions, such as those of the PGRFA, that are working towards an agreement on a standard MTA document.[62]

7. CASE STUDY: RIKEN

7.1 *Outlines of RIKEN*

RIKEN[63] is one of Japan's most distinguished public research institutes in the natural sciences. Its history began in 1913, when Jokichi Takamine, a Japanese scientist who discovered Taka-diastase and adrenaline, pointed out the need for a national science-research institute. Through the ef-

forts of Takamine and others, including Eiichi Shibusawa, a businessman who greatly contributed to Japan's industrialization in the early 20th century, a bill to establish RIKEN was passed by the 37th Imperial Diet in 1915. A "*Proposition relating to the establishment of RIKEN*" was submitted to the government in 1916, followed by a "*Bill for governmental subsidy of a semipublic organization to conduct research in the physical and chemical sciences.*" RIKEN was eventually founded in 1917 as a private research foundation.

In 1927, Rikagaku Kogyo was incorporated exclusively to make marketable products from RIKEN's inventions. In other words, Rikagaku Kogyo had a similar function to a TTO.[64] Subsequently, other new companies were created to manufacture the products. By 1939, there were 63 companies and 121 plants. The group was called RIKEN Industrial Group, otherwise known as "*RIKEN* Konzern." It included some successful companies, such as RICOH, that survived and flourished even after the dissolution of the Konzern. RIKEN registered 0.7% of all patents registered in Japan during the period from 1918 to 1944 and actively transferred its technologies to the RIKEN Konzern companies, many of which were commercialized. Simultaneously, the proportion of royalties from patents as a percentage of RIKEN's entire revenue dramatically increased from 0% in 1927 to 48.4% in 1939, reaching a high of 60.4% in 1940.[65]

Dissolved by the General Headquarters of the Allied Powers after Japan's defeat in World War II, RIKEN was later reorganized and incorporated as a private corporation called Kaken Kagaku Ltd. (Scientific Research Institute Ltd.) in 1948. The corporation covered its research expenses with royalties earned by out-licensing its inventions. However, royalties gradually became insufficient to cover research costs, so government funding became necessary.

RIKEN was reinvented and inaugurated in 1958 as a special public institution operated by the RIKEN Law, for comprehensive research in science and technology under the jurisdiction of the Science and Technology Agency (STA, later integrated as the MEXT). In October 2003, special public institution reforms by the government reorganized RIKEN into an independently managed administrative institution. Since the reorganization, RIKEN and other public research institutions and national universities (see Section 3) have had more independence and autonomy to make decisions about research activities and finances. On the other hand, this greater responsibility requires more transparency and accountability in relation to fiscal and administrative management.

RIKEN's total budget in fiscal year (FY) 2005 was 86,769 million JPY. Medical science and bioscience account for large shares of the budget. Funding is provided by the government (about 80%) and by RIKEN itself (about 20%).

RIKEN has full-time and part-time employees. Full-time employees are either permanent or contract-based employees (usually one-year and renewable). The number of full-time employees is approximately 3,000, more than 70% of which were contract-based in FY 2005. Part-time workers also number about 3,000. Both full-time and part-time employees include foreign researchers. The total number of foreign researchers has increased from 352 in FY 1993 and 519 in FY 1998 to 576 in FY 2002. Chinese researchers account for a quarter of the foreign researchers at RIKEN. Many other foreign researchers come from Korea, the United States, France, and Russia. The portion of researchers from European countries has expanded gradually, but China consistently is most strongly represented. RIKEN's personnel reflect a diversity of positions and backgrounds—a significant asset in today's globalized world.

RIKEN is headquartered in Wako, Saitama, and there are eight other RIKEN research sites across Japan's mainland. Each one specializes in a specific research field. In addition to the domestic branches, RIKEN has three overseas branch institutes: one in the United Kingdom and two in the U.S. Research facilities have been established at these locations in collaboration with the host laboratories. In April 2006, RIKEN launched an office at Biopolis, a biomedical research hub in Singapore with both public and private sector researchers. In partnership with regional research institutions and Singapore's Agency for Science,

Technology, and Research (A*STAR), this new office is a hub for research collaboration in Asia.

RIKEN has always collaborated with domestic universities and built close ties by accepting their research students. In addition to graduate-student partnerships with 23 Japanese universities as of 2005, RIKEN has established similar partnerships with several universities in other Asian countries. RIKEN jointly conducts various official research projects with over 50 overseas research institutes—unofficial collaboration and exchanges of material and information greatly swell this number.

7.2 *RIKEN's IP policy and strategy*

Under the RIKEN law, the institute's objectives are to conduct comprehensive research in science and technology and to disseminate research results. RIKEN carries out research in many fields, including physics, chemistry, medical science, biology, and engineering, that ranges from basic research to practical application. In its previous role as a special public institution, RIKEN emphasized basic research over practical research. In the last few years, however, the institution has focused more on practical applications. Especially since becoming an independently managed administrative institution in 2003, RIKEN has emphasized earning its own funds through commercialization, instead of relying on government funds. As part of this effort, RIKEN established the Center for Intellectual Property Strategies (CIPS) in April 2005.[66] CIPS was charged with handling IP policy, strategy, and management. CIPS addresses these issues comprehensively and has been able to deal successfully with the increasing numbers and varieties of researchers, laboratories, centers, and institutes within RIKEN.

7.2.1 *IP status*

Figure 2 shows the number of patents newly filed each year and retained by RIKEN domestically and overseas. The number of newly filed domestic and overseas patents has gradually increased, while the number of domestically owned patents has generally decreased. Overseas ownership has gradually increased. These trends have two important implications:

For one, RIKEN's efforts to file IP rights (principally patent rights) for as many inventions as possible, whether domestic or overseas, have increased the number of patent filings. Also, RIKEN has become increasingly selective in retaining its patent rights because to do so is costly. Every year, owners are required to pay on patents, not only filing and registry fees, but also maintenance fees. RIKEN's status as an independently managed administrative institution has made it adopt a more cautious approach to retaining patent rights. It has decided which patents to abandon by reviewing and assessing the value of each invention in terms of its potential profit and licensing prospects. This is another reason why the number of domestic patent rights has declined. For overseas patents, the selection was less pressured because it is more difficult to identify the value of each invention for the international market. Consequently, the number of overseas patent rights retained has increased—in FY 2003 it outnumbered the domestic.

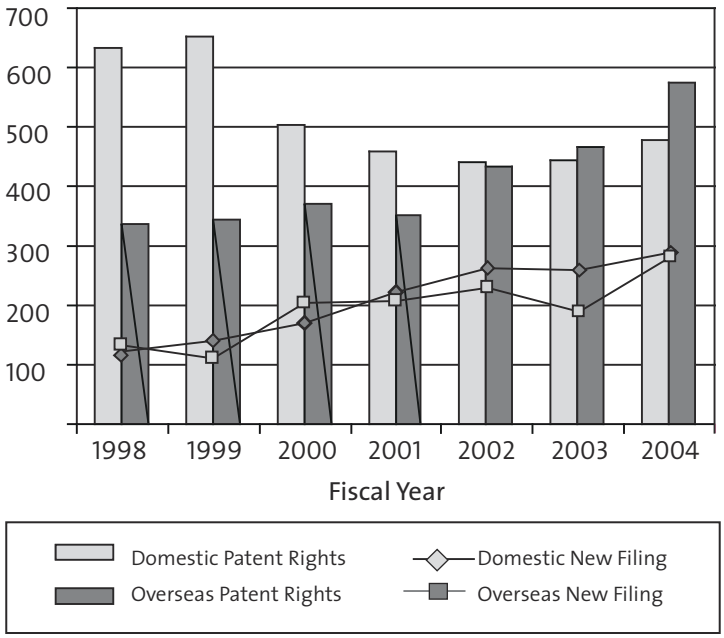
Figure 3 shows the number of licensed patents owned by RIKEN and the royalties earned through licensing each year. RIKEN's exploitation/licensing rate[68] is currently about 12%. This is below RIKEN's own expectations—as are the royalty amounts earned—so it is assumed that many of the inventions generated at RIKEN are not practical for commercialization. RIKEN has made the following efforts to raise the rate:

7.2.2 *Objectives for IP policy*

RIKEN's fundamental IP policies are driven by three main objectives: (1) to promote greater protection of IP rights on inventions, particularly patent rights; (2) to partner with industry; and (3) to generate profits through licensing.

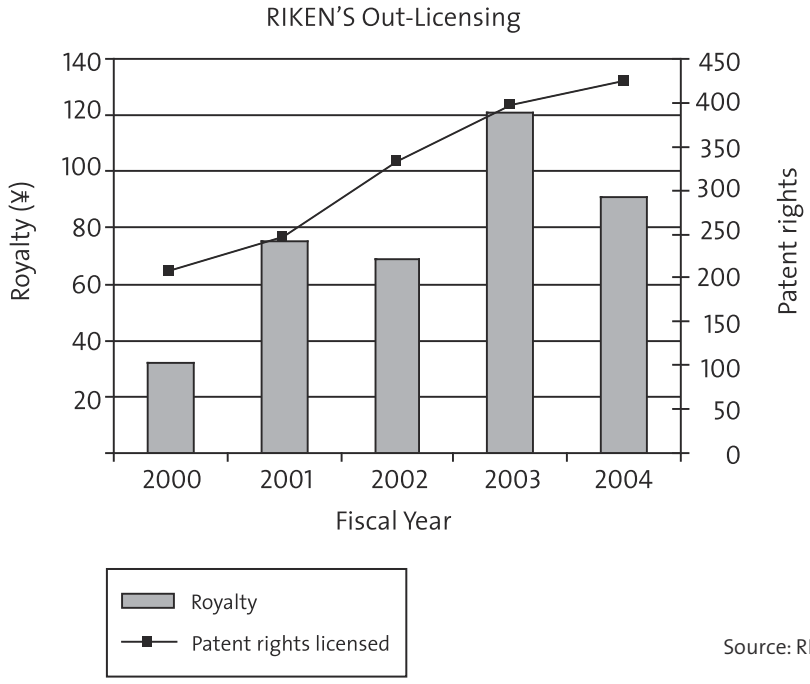
1. **Promotion of IP rights.** The promotion of activities relating to filing patent rights is aimed at contributing to the public domain by disclosing RIKEN's inventions through patent applications and at generating profits through licensing patented inventions to industry.
   (A) ***Patent liaison staff.*** To promote IP protection, RIKEN deploys about 10 staff members called "patent liaison staff."

Figure 2: RIKEN's Patent Rights (Retainment and Newly Filed)



Source: RIKEN CIPS[67]

Figure 3. The Number of Licensed Patents Owned by RIKEN and the Royalties Earned



Source: RIKEN CIPS[69]

Their responsibilities range from identifying inventions to protecting them through consultation with RIKEN's inventors. The staff is made up of qualified patent attorneys; incumbent staff employed and temporarily transferred by private companies or attorneys' offices with relevant experience; and retirees of private companies. There is no staff member with tenure deployed for patent liaison. It is felt that none of RIKEN's tenured staff have adequate knowledge and experience in IP and technology management because staff are rotated to other divisions every three or four years under the organization's personnel policy.

(B) ***Employee invention regulations.*** Compared to other public institutes in Japan, RIKEN set up regulations for employee inventions comparatively early. The regulations were amended in April 2004. Previously, employee inventors had to decide whether to retain ownership of an applied or registered patent (or other form of IP right) jointly with RIKEN—and shared equally—or to waive the whole right to their invention and assign it to RIKEN. If they decided to own half, they were required to bear half of the expenses for applying, registering, and retaining the IP (RIKEN paid the other half). Meanwhile, the employee could benefit from a variable percentage of the royalties that would be paid based on the amount of received royalties. Furthermore, a fixed amount of remuneration was paid to the inventors for both the application and registration of the patent. RIKEN was seeking to promote patent rights, and to encourage researchers to make more inventions, with the potential for economic returns by providing remuneration to the inventors.

The new regulations of April 2004, however, eliminated the inventor's option to own half the IP rights. The whole right would from then on be owned solely by RIKEN. The rationale for the change was that sole ownership by RIKEN would enable the institution to manage the entire technology transfer process, enabling it to determine licensing issues itself and to decide upon licensing details. The licensees are also likely to welcome RIKEN's sole ownership because the process is easier. Moreover, the number of one-year employment contracts within RIKEN has greatly increased over the last few years. Most researchers and inventors are newly employed and could resign one or a few years later. This fluidity makes it difficult to jointly own IP because the institute has to chase down inventors who have left RIKEN in order to obtain consent for exploiting or waiving rights. Besides, a number of inventors had not, in fact, chosen the option of joint ownership in the previous system. This was largely because of the risk and ambiguity involved in exploitation, as well as the high costs of applying for, registering, and retaining patent rights.

Another amendment relates to provisions for remuneration. The remunerations for application and registration were combined and paid together one year after the application, while the provision related to remuneration for licensing remained as it was. This amendment was a result of the increased fluidity of personnel: the registration process takes a few years—during or after which time the inventor may have left RIKEN—making the payment procedure ineffective.

(C) ***Raising Awareness***. RIKEN has made efforts to promote IP by raising awareness. Seminars and consultations about various IP rights issues are regularly held in not only the headquarters but also the branch institutes and centers. Because the frequent turnover of employees hinders the diffusion of knowledge about

RIKEN's IP policy and strategy, RIKEN requires newcomers to attend specific explanatory lectures that are held several times a year. This is in addition to the regular IP rights seminars. As a consequence of those efforts, the number of IP rights applications by RIKEN has been increasing.

2. **Partnership with industry.** RIKEN belongs to the academic sector. It makes a public contribution by providing the seeds of innovation to industry. Since becoming an independently managed administrative institution, generating profits through licensing has become increasingly significant for RIKEN. Its IP strategy focusing on partnerships with industry is a tool that allows RIKEN to generate social and economic returns simultaneously.

   Such partnerships involve not only technology transfer but also research collaboration. CIPS is highly involved in coordinating, funding, providing research space, and hosting industrial researchers for the collaboration. One of the programs RIKEN/CIPS formally organizes is the Fusional Cooperative Research Program. Started in 2004, the program transfers researchers employed by private companies to RIKEN to conduct collaborative research for several years. Under contract with RIKEN, the researchers can become team leaders of their research in RIKEN. RIKEN has published on its Web site[70] a database of its researchers who have registered for this program. The database includes their research activities and interests. A private company interested in a RIKEN researcher and his/her research applies for the program with a collaborative research proposal. The collaborative research under the program enables the rapid commercialization of the technology by the parallel creation of "seeds" and "needs" from the very beginning of the research planning stage. RIKEN contributes research expertise and facilities, and the private company contributes commercialization expertise and shares management tools to increase efficiencies. Expenses are borne by both RIKEN and the private company. The contracted term is generally five years. As of April 2006, ten teams have been created and are pursuing collaborative research under the program.

3. **Promotion of exploitation.** RIKEN has adopted some strategies to promote the exploitation of inventions that its researchers generate. These strategies include disseminating information about patents owned by RIKEN, coordinating and facilitating technology transfer, and the "RIKEN Venture" system.

(A) ***Disseminating information about patents owned by RIKEN***. RIKEN has actively tried to promote the exploitation of inventions by disseminating information about its patents, which is expected to increase private companies' abilities to find and exploit them. Information is disseminated via the *Journal of RIKEN Patents* published by CIPS. A patent database is published online at the R-BIGIN (RIKEN-Business Information for Global IP Network) Web site, and RIKEN also exhibits its technologies at external fairs relating to technology transfer.

(B) ***Coordination of technology transfer***. RIKEN deploys several coordinators in CIPS to increase the transfer and exploitation of its technology. Similar to the patent liaison staff, the coordinators include current private sector employees, who have been temporarily transferred to RIKEN, and experienced retirees from the private sector. Their responsibilities are to search for licensees, negotiate terms, and conclude licensing contracts. In addition to the coordinators, RIKEN outsources contracts to some large enterprises to coordinate technology transfer with private companies. These enterprises have varied, detailed information about potential licensees, and this external coordination facilitates technology transfer from RIKEN to industry.

(C) *The RIKEN Venture system.*
Set up in 1998, RIKEN Venture system supports and encourages employees to establish and operate private companies based on inventions generated at RIKEN. In addition to enabling RIKEN employees to retain a post at the private company, RIKEN provides preferential treatment to the company:
- RIKEN licenses its patent rights relating to the invention exclusively to the company
- RIKEN allows the company to utilize its research space and facilities for collaborative research with RIKEN
- RIKEN provides the company with office space and equipment for management at preferential rates

These advantages make it easier for inventors to exploit and distribute their own inventions to the public, which creates yet another incentive for researchers to make or adapt practical, profitable inventions. Additionally, innovations that existing companies find difficult to exploit can be given another chance by their inventors. The program offers support to each company for five years, which can be extended for an additional five years. As of July 2005, the program has supported 16 companies: seven are in the field of biomedicine.

7.3 *RIKEN BioResource Center (BRC)*

In 2001, RIKEN founded the BioResource Center (BRC)[71] at the Tsukuba Research Institute. After a gene bank service was established at RIKEN in 1987, the BRC was founded to expand the scope of the collected resources. The Japan Collection of Microorganisms, which had initially been established at RIKEN headquarters, was integrated within the BRC in 2004. Integration enabled the BRC to offer a distribution service for a wide range of resources including animals, plants, cells, genes, and microorganisms. The RIKEN BRC has been supported by Japan's national bioresources project.

The principal contribution of the BRC to life sciences research is to collect, preserve, breed, and distribute biological resources to and from researchers in Japan and overseas. Other BRC activities include the development of bioresources and new technologies to increase their value. The BRC has made a great effort to foster transfers of bioresources for both collection and distribution since its foundation. All transfers are carried out based on the conclusion of MTAs, for which RIKEN has created its own forms and procedures. Although some details vary among the types of resources, the grounds for transfer are generally as follows:

1. Collection (resources are deposited or assigned by originators).
   - An MTA must be concluded between RIKEN BRC and the originator for the deposit/assignment. The MTA form for deposit or assignment is provided by the BRC.
   - The originator is entitled to choose to deposit the resources and retain the IP rights to the resource or to assign the resource with the IP rights to RIKEN.
   - Whether it is a deposit or an assignment, resources are collected by the BRC without any remuneration to the originator. (RIKEN bears the expenses of shipment for collection.)
   - In addition to the requirements set by RIKEN BRC, a third party's minimum requirements for using resources, such as acknowledgement in publication of research results, can be added to the MTA by the originator.
   - By the deposit/assignment, the originator can, for no charge, be credited and provided with other resources collected by the BRC, according to the number of resources that he or she provides.
2. Distribution (resources are transferred from the BRC to a third party [recipient/user] for their research use).
   - An MTA between RIKEN BRC and a user must be concluded and signed for the distribution to occur. The MTA form is provided by the BRC.

– The user bears the expenses of shipping, handling, part of production, and other costs related to preparing or distributing the resources. Allocations of costs are differentiated between public and private partners, with private partners assuming the greater burden.
– The user is required to specify a research theme for which the resources are used. If resources are used for another theme, prior notification to the BRC is required.
– When research results that used the resources are published, the user is required to make it clear that the resources were provided by RIKEN BRC.
– The user cannot transfer or make the resources available to other parties for any purposes.

The BRC is becoming recognized as one of the major bioresource centers in the world. Furthermore, the BRC/Experimental Animal Division is one of the founding members of the Federation of International Mouse Resources (FIMRe),[72] along with such outstanding mouse resource centers as the Jackson Laboratory (U.S.) and European Mouse Mutant Archive (EMMA). The FIMRe is a collaborating consortium group of mouse repository and resource centers worldwide whose collective goal is to archive and provide to the research community strains of mice, as cryopreserved embryos and gametes, embryonic stem (ES) cell lines, and live breeding stock. The mouse-strain resources deposited or assigned to the RIKEN BRC—and related pieces of information—are registered and published on the database of the FIMRe, known as the International Mouse Strain Resource (IMSR),[73] Registration promotes and facilitates global access by researchers to BRC resources. Additionally, the RIKEN BRC receives complementary support for the specific management of IP protected microorganism collections from NITE, which is under supervision of METI. This interagency collaboration facilitates the coordination of R&D.

8. CONCLUSION

Japan's patent system was established at the end of its national isolation policy. The system is reasonably effective. Emphasizing the importance of national and institutional IP management in its policy and strategy for national development over the last decade, the government has revised aspects of the patent law and reformed related systems, including those related to national universities and public institutions. Some of the revisions and reforms have been geared towards international harmonization and the adoption of precedence established in other countries. Others have been intended to establish *sui generis* laws and systems to suit the country's unique interests. Despite this progress, some issues and arguments have yet to be conclusively addressed.

Regarding collaborations between industry and academia, for example, the reform of national universities and public institutions in the early 2000s has catalyzed partnerships, largely because of the expanded freedom and responsibilities given to universities by the government. Over the last decade, universities have established TTOs in order to create, transfer, and exploit IP rights derived from their research projects, an increasing number of which are carried out in partnership with industry. Nevertheless, human resource shortages plague the system. Personnel with expertise in both legal and technical aspects are especially in demand.

Since the early stages of Japan's industrial development, the Patent Law has made provisions for employees' inventions. Over the last decade, an increasing number of institutions and companies have recognized the significance of rules and regulations for employees' inventions and taken steps to establish them. This has been supported by the new government's policy and strategy: a Nation Built on IP. In 2005, the provisions (Article 35 of the patent law) were amended in favor of inventors so that the criteria for remuneration for inventions would be reasonable for them. Since a few years prior

to the amendment, the number of lawsuits in which a former employee sued his or her former employer because of dissatisfaction with their remuneration has increased. Some lawsuits have been settled, but various questions remain unresolved.

Japan's IP system and management is in some ways unique in relation to the health and agriculture sectors. IP rights for health care have been recognized as publicly shared knowledge and skills with equitable properties rather than personalized trade secrets or proprietary knowledge and skills, although some incentives have been furnished to enable the sharing and development of individual invention and know-how. Agriculture has traditionally been in the public domain, while specific technology has been protected as individual trade secrets. In the past, crop varieties were recognized as common heritage. Due to plant variety protection law and the recent paradigm shift in international and domestic arenas affecting IP laws, however, the use and status of the varieties has been in question, with business incentives rather than the public good driving the changes.

Overall, the stakeholders in health and agriculture will recognize IP increasingly in Japan. Diverse ways of adapting IP protection are being considered, and a *sui generis* approach may be adopted to tackle many subjects. Public awareness is likely to be promoted through public engagement in IP management, particularly in health and agriculture. ■

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Box 1: Situation and Precedents Relating to Limits of Patent Rights Regarding Medical Methods

Country/Region	Law on limits of patent rights Situation and precedents on: (A) Experiment or research (B) Clinical trials of generic medicines (C) Experimental use in universities
Japan	**Article 69** (1) The effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research. (A) The theory that has been the most widely accepted is the one that limited the experiment or research applicable to Article 69 (1) to those for the purpose of "progress in technology." (B) Many theoreticians assert that private companies cannot use others' patent rights in clinical trials (for obtaining regulatory approval for manufacturing generic medicines), but past legal judgments have been variable and reflected both sides of the argument. The Supreme Court's judgment in 1999, however, set a legal precedent that confirmed that trials for the purpose of obtaining regulatory approval should be exempt. (C) Historically, in determining cases of exemption, the courts have not distinguished between university and industry (private companies). That is, there is no exemption for universities because of their academic and educational nature. However, based on the principle that experiment/research aimed at technology advancement is exempted from infringement, university-based experiment/research is congruently exempted.
United States	**35 U.S.C.** **271 (e)(1) ("Bolar Provision")** It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product [as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913] which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(Continued on Next Page)

Box 1 (continued)

United States (continued)

(A) Experiment or research using patented products for commercial purposes is considered to be an infringement. The Federal Circuit Court of Appeals has reconfirmed in several cases that the scope of exemption from infringement in relation to experimental use should be very narrow.

(B) The case of *Eli Lilly & Co. vs. Medtronic, Inc.* in 1990 confirmed that the Bolar Provision (inserted into U.S. patent law in 1984) covers clinical trials using not only medicines but also medical tools, but the application of the Bolar Provision is limited to the development and submission of information to the FDA (Food and Drug Administration).

(C) With regard to experimental use in universities, there have been very few cases. One is the case of *Madey vs. Duke University* in 2002, which confirmed that the scope of exemption should be very narrow. The exemption was not applied in this case.

European Union

EPC (European Patent Convention) Article 64

Rights conferred by a European patent: (3) Any infringement of a European patent *shall be dealt with by national law.*
CPC (Community Patent Convention), Article 27, Limitation of the effects of the Community patent. The rights conferred by a Community patent shall not extend to:
(a) acts done privately and for noncommercial purposes;
(b) acts done for experimental purposes relating to the subject matter of the patented invention; etc.

United Kingdom

Patent Act 1977
Article 60

Section 5. An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if:
(a) it is done privately and for purposes which are not commercial;
(b) it is done for experimental purposes relating to the subject matter of the invention, etc.

(A) Experiment or research using patented products for commercial purposes are distinguished between those trials in which products are merely being tested for quality, which are exempted, and others in which they are being demonstrated

(Continued on Next Page)

Box 1 (continued)

United Kingdom
(continued)

to a third party or used for quality enhancement in other products provided to a third party, which are considered within the scope of infringement.

(B) The trials and manufacturing of patented products for the purpose of obtaining regulatory approval is out of the scope of exemption and regarded as patent infringement.

(C) There have been no cases establishing precedent relating to experimental use in universities.

Germany

(1) Patent Law
11. (Amended in 1981)

The effects of a patent shall not extend to:
1. acts done privately and for noncommercial purposes;
2. acts done for experimental purposes relating to the subject matter of the patented invention; etc.

(A) Experiment or research using patented products either to obtain information regarding the subject of the patented products (for noncommercial use) or to enable scientific investigation is exempted from patent infringement. From the viewpoint of public benefit, patent rights do not extend to cases interfering with technological progress.

(B) In the Clinical Tests II case in 1997, it was confirmed that trials to clarify areas of uncertainty or trials aiming at acquisition of new knowledge relating to the subject of the patented products fall under the scope of exemption.

(C) There have been no cases establishing precedent relating to experimental use in universities.

France

Intellectual Property Law
Art. L. 613-5. (Amended in 1978)

The rights afforded by the patent shall not extend to:
(a) acts done privately and for noncommercial purposes;
(b) acts done for experimental purposes relating to the subject matter of the patented invention; etc.

(A) The case of *Babolat vs. Redeye* (1992) set a precedent that experimental use for the purpose of evaluating the commercial effect of a patented product on consumers would be considered an infringement.

(Continued on Next Page)

Box 1 (continued)

France
(continued)

(B) The cases of the *Wellcome Foundation Ltd. vs. Parexel International, Flamel Technologies & Créapharm* (2001) and *Science Union & Servier vs. Expanpharm* (2002) confirmed that trials for the purposes of obtaining regulatory approval for substitutes of marketed medicines (that is, generics) and of obtaining regulatory approval fall under the scope of exemption.

(C) There have been no cases establishing precedent relating to experimental use in universities.

Republic of Korea

Patent Law 96

(1) The effects of the patent right shall not extend to the following:
  (i) working of the patented invention for the purpose of research or experiment; etc.

(A) There have been no cases establishing precedent relating to experimental use.

(B) There have been no cases establishing precedent relating to clinical trials. Theoreticians regard this as exempt from infringement.

(C) There have been no cases establishing precedent relating to experimental use in universities.

China

Patent Law, Article 63

None of the following shall be deemed an infringement of the patent right:
(4) Where any person uses the patent concerned solely for the purposes of scientific research and experimentation.

(A) Exemption is not always applicable in cases relating to experimental use in general R&D activities. Exemption from infringement applies when experimentation relates to technical appraisal of patent rights and regarding the patented technology per se.

(B) It is generally considered that clinical trials for the purpose of obtaining regulatory approval are not an infringement if undertaken within two years of the patent expiration date.

(Continued on Next Page)

Box 1 (continued)

China (continued)	(C) There have been no cases establishing precedent relating to experimental use in universities.
Singapore	**Patent Act** 66.-(2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if: (a) it is done privately and for purposes which are not commercial; (b) it is done for experimental purposes relating to the subject matter of the invention; (h) it consists of the doing of any thing set out in subsection (1) in relation to the subject matter of the patent to support any application for marketing approval for a pharmaceutical product, provided that any thing produced to support the application is not: (i) made, used, or sold in Singapore; or (ii) exported outside Singapore, other than for purposes related to meeting the requirements for marketing approval for that pharmaceutical product; etc. (A) There have been no cases establishing precedence or coherent theory regarding the exemption of experimental use as Singapore's patent system and law is rather young (since 1994). (B) The Amendment to the Patent Act in 2004 exempted clinical trials for the purpose of obtaining regulatory approval. (C) There have been no cases establishing precedent relating to experimental use in universities.
India	**Patent Act** 47. The grant of a patent under this Act shall be subject to the condition that: (3) any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils; and etc.

(Continued on Next Page)

Box 1 (continued)

India
(continued)

107A. For the purposes of this Act:
(a) any act of making, constructing, using, selling, or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale, or import of any product;
... shall not be considered as an infringement of patent rights.

(A) There have been no cases establishing precedent or coherent theory regarding the exemption of experimental use.

(B) The Amendment to the Patent Act in 2002 (Sec. 107A) exempted clinical trials for the purpose of obtaining regulatory approval.

(C) There have been no cases establishing precedent relating to experimental use in universities.

TRIPS

TRIPS Article 30

Exceptions to Rights Conferred
Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Source: *Tokkyohatsumei-no enkatsu-na shiyou-ni kakawaru shomondai-ni tsuite* (Report on issues relating to effective use of patented invention)[47]