

Intellectual Property Management at Japanese Universities

Japan Patent Office
Asia-Pacific Industrial Property Center (APIC), Japan
Institute for Promoting Invention and Innovation

©2016

Collaborator: Kenichi Hatori
Project Professor
Keio University Graduate School of Science
and Technology

Table of Contents

1. Third University Mission—Social Contribution—	1
1. Japan’s Declaration to Become an IP-Based Country	1
2. From the Amendment of the Basic Act on Education to Technology Transfer & University-Industry Collaboration	2
3. Structure of Technology Transfer and University-Industry Collaboration	3
4. Conversion of Research Results into Benefits for Society	5
5. Government Support	6
2. IP Management (System) at Universities	8
1. Introduction of the Japanese version of the Bayh-Dole Act (Act on Special Measures for Industrial Revitalization of 1999)	8
2. Invention Ownership (Employee Inventions at Universities)	9
3. Need for IP Management, and the Development and Penetration of IP Management Policy	9
4. IPMOs and TTOs (TLOs)	11
5. Cases of Student Invention	12
6. IP Education	13
3. From Invention Discovery to Technology Transfer	15
1. Entire Flow	15
2. Invention Discovery	17
3. Patent Filing	17
4. Foreign Patent Filing	18
5. Licensing Activities	19
6. Patent Maintenance	21
7. Infringement Discovery and Warning/Litigation	23
8. Patent Invalidation Trials	24
9. License Examples	24
4. Characteristics of University Patents, and Domestic and Foreign Patent Acquisition Practices	34
1. Paper and Patent — Taking iPS Cell Invention as an Example —	34
2. Grace Period and the American Invention Act (AIA)	37
3. Use of National Support for Foreign Application	39
4. Examples of Acquisition of University-Originated Patents Using a Support System	41
5. Provision of Patent Information to Researchers	42
1. University Missions and Use of Patent Information	42
2. Use of a Patent Map	43
3. Indispensable to Provide Patent Documents to Researchers in Regenerative Medicine	49
6. IP Management in Joint Research and Contract Research	54
1. Acquisition of Research Funds at Universities	54
2. Why Do Universities Conduct Joint Research (Tie Ups with Companies)?	55

3.	Flow of Joint Research, and Necessity of NDA	56
4.	Negotiations for a Joint Research Agreement	58
5.	Handling of Intellectual Property under a Joint Research Agreement	60
7.	University-Launched Startups	63
1.	Why Are Startups Necessary?	63
2.	Overview of University-Launched Startups in Japan.....	64
3.	Startup Examples.....	65
8.	Conflict of Interest.....	68
1.	What is a Conflict of Interest?.....	68
2.	COI Examples	69
3.	COI Management	71
9.	Expectations of Universities in Innovation Creation.....	73
1.	Toward a World of Open Innovation	73
2.	Technology Transfer, University-Industry Collaboration, and URA Training	74
3.	Network Building and Specialist Training	75
10.	Appendix	79
1.	Japanese Government Bodies for Technology Transfer, University- Industry Collaboration, and Human Resources Development	79
(1)	University-Industry Collaboration & Regional R&D Policy Division, Science and Technology Policy Bureau, MEXT	79
(2)	Industry-University Collaboration Office, Industrial Science and Technology Policy and Environment Bureau, METI.....	79
(3)	Foreign Advisory Unit, International Cooperation Division, Policy Planning and Coordination Department, JPO, METI	79
(4)	Asia-Pacific Industrial Property Center (APIC), Japan Institute for Promoting Invention and Innovation (JIII)	79
(5)	Japan Science and Technology Agency (JST).....	79
2.	University-Industry Collaboration and Technology Transfer Networks and Associations in Japan.....	80
(1)	University Network for Innovation and Technology Transfer (UNITT)	80
(2)	Intellectual Property Association of Japan	80
(3)	Japan Society for Intellectual Production.....	81
3.	Related Provisions of Patent Laws	81
(1)	Article 73 (Jointly owned patent rights), Patent Act	81
(2)	Patent Laws U.S.C. 262.....	81
(3)	Article 15, Patent Law of the People's Republic of China (Effective October 1, 2009).....	82

1. Third University Mission—Social Contribution—

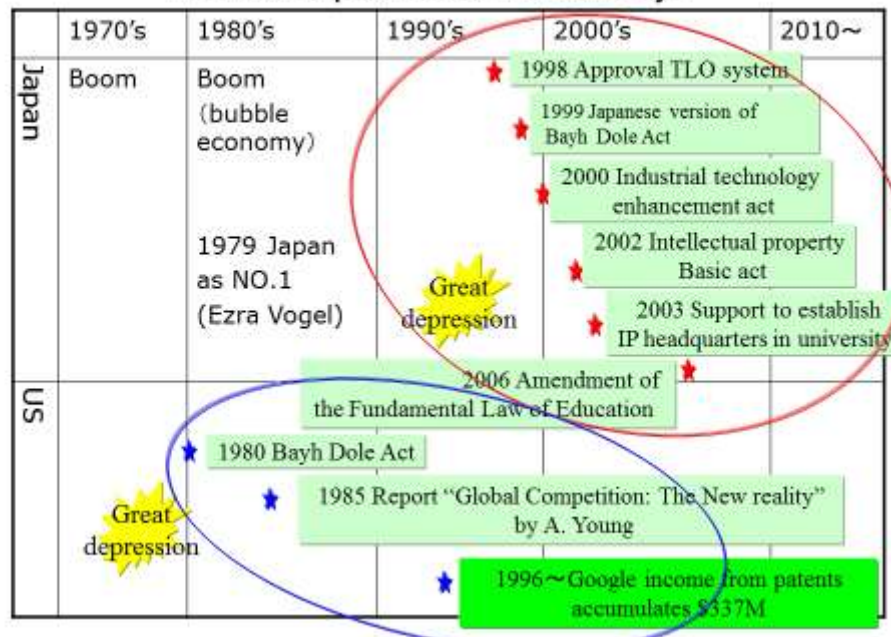
1. Japan's Declaration to Become an IP-Based Country

Back in 2002, Mr. Junichiro Koizumi, Japan's then prime minister, was the first to declare that Japan would establish itself as a country based on intellectual property (an "IP-based country"), placing intellectual property rights as a mainstay of the country's policy. From the 1970s through the 1980s, Japan enjoyed a period of high economic growth, which however eventually developed into a bubble. The bubble then burst and in the 1990s, a great depression hit the Japanese economy. To recover from the depression, the first major step the Japanese government took was its declaration to become an IP-based country.

The first program (Strategic Program 2003) in the move toward recovery focused on three areas of intellectual property: creation, protection, and exploitation. Great attention was brought to universities and research institutions as bearers of IP creation. With the Approved TLO System (See 1.5) and the Japanese version of the Bayh-Dole Act (See 2.1) introduced in 1988 and 1999 respectively, universities at that time were entering a new era. They not only served as academic institutions offering conventional education and research, but they were also undergoing structural changes geared toward putting their research results to commercial or industrial use.

This new change was modeled on the United States' example in the 1970s to the 1980s. In the 1970s, while the Japanese economy was booming, the US was at the bottom of a depression.

**Towards an Innovation Creation Nation based on IP strategy
-What is Expected of the University-**



The US worked out initiatives to exploit universities as a strategy to recover from the depression.

Popular among these were the Bayh-Dole Act introduced in 1980, the Young Report released in 1985, and the Federal Technology Transfer Act introduced in 1986.

Following these successful examples in the US, Japan launched initiatives to exploit universities, like the US, in an effort to recover from the post-bubble economic depression. Specifically, the country initiated university reform programs with a main focus on the Approved TLO System (See 1.5) in 1988 and the Japanese version of the Bayh-Dole Act (See 2.1) in 1999.

In the 1970s–1980s economic boom known as the “catch-up period,” Japan followed the US in advanced technology. Introducing advanced technology from the US, Japan successfully mass-produced and globally marketed uniform products, and put its economy on a high growth path. In the 1990s, however, the bubble burst, and developing countries began to produce cheaper products, devastating the Japanese business model and bringing the catch-up period to an end.

To maintain high global competitiveness in the coming eras, Japan needed to shift greatly to becoming a front-runner that could create new technologies on its own to produce and provide more value-added products and services.

What was needed to become a front-runner? One answer lay in universities, which had many research resources and conducted both basic and advanced research. Universities were expected to serve as sources of innovation.

2. From the Amendment of the Basic Act on Education to Technology Transfer & University-Industry Collaboration

The Japanese government amended the Basic Act on Education in 2006. Article 7 of this Act states that “Universities, as the core of scholarly activities, are to contribute to the development of society by cultivating advanced knowledge and specialized skills, inquiring deeply into the truth to create new knowledge, and broadly offering the fruits of these endeavors to society.” The statute was amended for the first time in 60 years since its promulgation in 1947 soon after the end of World War II. This interval of time may suggest how highly anticipated and epoch-making the amendment was.

Traditionally, universities had two missions: education and research. In addition to these, the amended law clearly states social contribution as the third university mission, stating that universities “are to contribute to the development of society by cultivating advanced knowledge and specialized skills.”

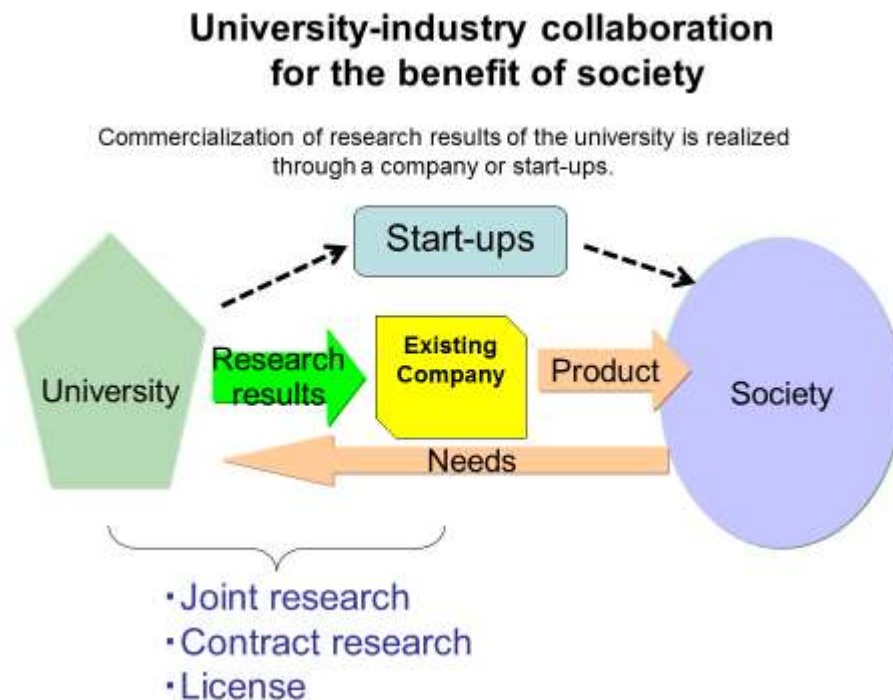
This third university mission—“social contribution”—is rooted in the Intellectual Property Basic Act promulgated in 2002. Article 7 of this Act states that “Universities, etc., shall, in light of the fact that their activities contribute to the creation of intellectual property throughout the whole society, endeavor voluntarily and positively to develop human resources and disseminate research and research results.” The words “endeavor voluntarily and positively to develop human resources and disseminate research and research results” exactly match the third university mission of social contribution. In this sense, the Basic Act on Education can be seen

to have been amended in the spirit of the Intellectual Property Basic Act.

How then should universities specifically disseminate and make their research results available to society? Universities are academic institutions, neither product manufacturers nor service providers. Therefore, universities can give university-originated research results back to society only by putting them into widespread use in society through cooperation with an existing company that commercializes the university research results, or via startups established by their researchers on their own research results. This is what is referred to as university technology transfer and university-industry collaboration.

3. Structure of Technology Transfer and University-Industry Collaboration

The methods of giving university research results back to society can be divided broadly into two: (i) via an existing company and (ii) via a startup established by researchers (inventors). In the case of (i) giving back via an existing company, it is customary to do so under a joint research or contract research agreement or a licensing agreement between the university and the company.



However, it is often regarded as highly risky for companies to accept such agreements, partly because university research results are basic and not sufficiently refined for proceeding toward commercialization. In the case of refusal, which makes it impossible to give the results back to society via an existing company, researchers (inventors) may establish a startup by themselves. This is the method of (ii) giving research results back to society via a startup. As mentioned above, universities often create research results with a low probability of commercialization, but rather of the high-risk high-return type that may lead to lifestyle innovation in the world.^(Note*) In many cases, such high-risk research results end in failure. However, some startups, like Google, have taken such risks and succeeded in developing such innovative research results into practical applications. It is greatly significant therefore for

universities to support startups, considering the magnitude of the impact that startups, despite their low success rates, may have if successful.

Note*: THE NATIONAL ACADEMIES (2011). Managing university intellectual property in the public interest. THE NATIONAL ACADEMY PRESS, pp.26

4. Conversion of Research Results into Benefits for Society

Universities are academic institutions and do not aim to pursue profits like companies. To give their research results back to society, however, universities need license income in accordance with the nature and scale of the technology transfer activities to maintain the activities as a vital means of giving back. The costs of technology transfer activities may cover (i) patent filing and maintenance costs, (ii) personnel costs of the technology licensing organization (TLO) staff, (iii) incentive costs to inventors, and (iv) incentive costs to research institutes, faculties, and other university organizations. Of these, (i) and (ii) are minimum necessary costs. If such costs are not covered by income, the TLO cannot remain in place.

To act more strategically, the TLO also needs the budget to raise basic research results to a level worthy of attracting interest from companies, or to support additional research and development to make trial products.

It seems desirable for the benefit of society to (i) keep license fees as low as possible, (ii) make licenses non-exclusive, not allowing certain enterprises to hold monopolies on licenses, and (iii) give priority to domestic small and medium-sized enterprises (SMEs) in licensing state-funded research results. However, consideration should also be given to the balance necessary to ensure that the TLO can maintain its activities. There are many examples where patented inventions are made available by exclusive license and developed into practical applications.

As examples, the following provides two cases of licensing at Stanford University (US) to consider the positioning of licensing:

http://otl.stanford.edu/about/resources/about_resources.html?headerbar=0

(Case 1) Licensing of recombinant DNA technology

According to the Stanford University OTL (Office of Technology Licensing) website, this invention relates to DNA cloning, and is a key technology for the early-stage biotechnology industry. The invention has been widely licensed on a non-exclusive basis to 440 companies, with a cumulative royalty income of 225 million dollars allocated to Stanford University and the University of California. This is a good example of giving back to society, in that the invention has been licensed to anyone who wished to use it for a low license fee. Meanwhile, the low license fee has lowered the bar to using the technology, promoting the widespread use of it enough to establish it as the de facto standard and bringing a large licensing income to the university. This idea of licensing would be basically the same as FRAND (fair, reasonable and non-discriminatory), a core idea behind patent pooling.

(Case 2) Licensing of the Google search engine

According to the Stanford University OTL website, one day, two young graduate students came into the OTL office with a new search engine. At that time, nobody knew whether any company would show interest in the technology. They eventually developed four search engines and introduced them to companies, but none of the companies showed any interest after all. However, the inventors, Larry Page and Sergey Brin, were really convinced that their invention was a superior technology. Unsatisfied that no companies were interested in their search engine, they then decided to start a business on their own. The OTL granted an exclusive license for

this startup. Page and Brin have since made their startup into the giant it is today. In this case, the granting of an exclusive license to the startup, whose search engine has come into widespread use around the world, has in turn brought Stanford a royalty of 340 million dollars in license income. As startups lack human resources and funds, this example indicates that exclusive licensing can be effective for startups.

5. Government Support

From early on, the Japan Patent Office (JPO) has worked on a system to dispatch experts in intellectual property rights (IPRs) and technology transfer (“patent licensing advisors”) to universities and other institutions to give university research results back to society. The Commemorative Publication for the 125th Anniversary of the Japanese Industrial Property System, released by the JPO in 2010, states in Section 1 Initiatives to Activate IP Activities, Chapter 8 Patent Licensing Promotion (Note 3) that the JPO started a patent licensing advisor program in 1997, dispatching 14 patent licensing advisors to local governments. In the following year, 1998, when the Approved TLO System went into operation (see 2.4), the JPO started dispatching patent licensing advisors to TLOs at universities, with the total number of advisors dispatched increasing to 39. After that, the scale of dispatch has continued to expand, and then exceeding 100 advisors to local governments and TLOs.

The duty of the patent licensing advisor is defined as “uncovering transferable or licensable patented technologies owned by universities, public research institutions and companies, and understanding the technological needs of SMEs and startups to make matches between these technologies and needs.” This definition indicates that the patent licensing advisor’s duty can be translated as the service of technology transfer from universities or other institutes. Patent licensing advisors have contributed greatly to the core TLO (TTO) operations of discovering inventions at universities and selling them to companies. In addition, a strong network has been formed between patent licensing advisors, enabling them to share skills and exchange useful information, which has led in turn to the advisors pursuing their activities more vigorously and delivering successful results.

In 1998, moreover, the Act to Facilitate Technology Transfer from Universities to the Private Sector (the “TLO Act”) came into force, and a policy framework to support the setting up of TLOs (currently frequently called TTOs, or technology transfer offices) entered into operation under the joint supervision of the Ministry of Economy, Trade and Industry (METI) and the Ministry of Education, Culture, Sports, Science and Technology (MEXT). As a result, mainly major universities in Japan began to set up a TLO (TLO) on campus or off campus (see 2.4 for details). These setups were supported, for example, by government subsidization of up to 30 million yen within a subsidy proportion of two-thirds (2/3) for five years to enable the TLO (TLO) to employ technology transfer experts. Consequently, an occupational group of technology transfer was systematically formed. Meanwhile, the JPO supported TTOs (TLOs) by having examination fees and patent fees with reduced rate of 1/2 (for the first year to the third year).

In 2003, MEXT started to support the establishment of intellectual property offices (IPOs) at universities (up to 2007). This support was provided in the form of subsidization. The subsidy was appropriated mainly for the employment fee of

technology transfer experts, the most necessary factor for IPOs, and for activities by such experts from invention discovery through IP right acquisition to licensing.

In 2008, MEXT started to support universities in promoting international collaboration between industry, academia and the government. This support encouraged many universities to conduct international joint research and licensing activities with overseas companies.

In 2011, MEXT started to support the setting up of the posts of university research administrators (URAs) at universities. The introduction of URAs was aimed mainly at (i) assisting researchers in obtaining competitive funds for conducting research, (ii) supporting the management of these granted research funds, and (iii) supporting the exploitation of research results. Its goal was to create an environment that ensured that researchers could concentrate on their research.

As a result of MEXT having continuously supported universities in this way since 2003 to give research results back to society, a platform for university-industry collaboration and technology transfer has been established, with many universities grasping the importance thereof.

2. IP Management (System) at Universities

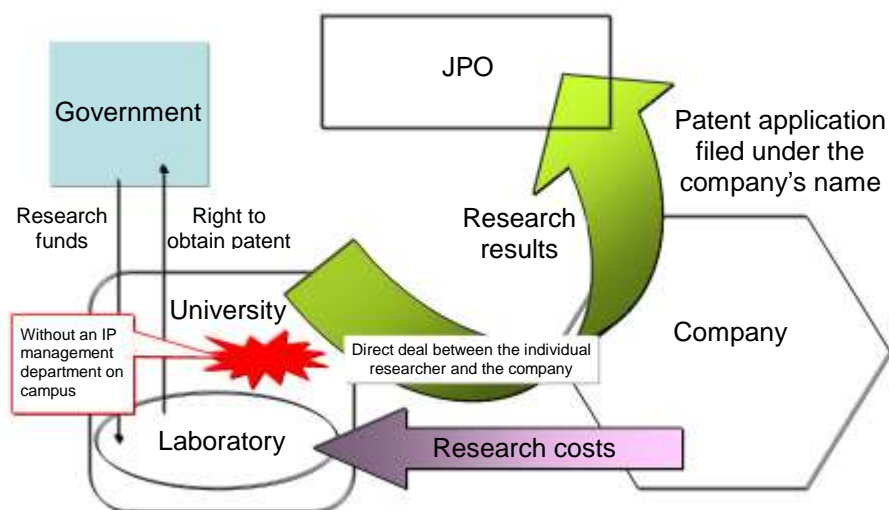
1. Introduction of the Japanese version of the Bayh-Dole Act (Act on Special Measures for Industrial Revitalization of 1999)

The Bayh-Dole Act was established in the US in 1980. Bayh and Dole are the names of the Senators who proposed this law. In the US before the enactment of this law, a system was in place whereby patent rights obtained by universities through federally funded R&D belonged to the funder, that is, the federal government. For this reason, university researchers were little interested in creating inventions. Moreover, many inventions created by university researchers were brought under government control and kept within the government without the provision of incentives to develop practical applications. In other words, huge research funds given to universities failed to contribute to industrialization in a visible form.

Since the enactment of the Bayh-Dole Act, however, universities have been allowed to retain ownership of the patent rights they have obtained. However, the law, intended to encourage the commercialization of university research results, has required universities as the owners of IPRs to endeavor to license research results.

Also in Japan, the Act on Special Measures for Industrial Revitalization was established in 1999, which prescribes the Japanese version of the Bayh-Dole Act. This has allowed universities to own the right to obtain patents for results from research on competitive research funds granted by the government, giving big incentives to inventors. As this Japanese version of the Bayh-Dole Act requires universities to manage on their own patent applications for inventions created with government-granted competitive research funds, the universities have established an internal organization that takes charge of patent filing and patent right management.

Former University-Industry Collaboration



18

2. Invention Ownership (Employee Inventions at Universities)

In 2002, MEXT issued a working group report (November 2002) compiled by the Intellectual Property Working Group under the Committee on the Promotion of University-Industry-Government Collaboration, Technology and Research Foundations Section, of the Council for Science and Technology (CST). The report provided a fundamental concept of shifting the ownership of rights to inventions created at universities, in principle, from the inventors (1977 Science Council Report, emphasizing raising motivation to create inventions) to the universities (emphasizing the exploitation of inventions). This revision has required the university to decide whether to file patent applications for the inventions, as its own property, which have been submitted by its researchers. Since the universities need to pay the representative patent attorney and the JPO a huge amount for patent filing, the universities should be prudent in making such decisions. For inventions for which the universities have decided not to file patent applications, they should, in general, disclaim the right to obtain patents for the inventions, and grant such right to the inventors if the inventors so wish.

This significant policy change means transferring the right to obtain patents from the individuals to the universities, in a direction that may seem different from the philosophy of the Bayh-Dole Act of 1999. However, the reason for the transfer of the right to obtain patents to the universities is to encourage the commercialization of university research results. The TTOs at the universities take charge of this commercialization, introducing transparency into and optimizing the procedures, thereby curbing the occurrence of conflict-of-interest scandals (see 8.1). In this way, researchers can rest assured that they are involved in technology transfer and university-industry collaboration. Therefore, the basic concepts and ultimate goals of the policy is the same as the law.

In other words, this policy change would be infrastructural upgrading and development for the creation of university-originated intellectual property that could be commercialized in the future for Japan to recover from its protracted depression.

3. Need for IP Management, and the Development and Penetration of IP Management Policy

Based on MEXT's 2002 CST working group report, a big shift has been effected in the ownership of the right to obtain patents for inventions created at universities, in principle, from individuals (researchers) to institutions (universities).

Universities must properly manage the intellectual property they have created to ensure the effectiveness of this big shift, and to ensure that they play their role in building an IP-based country. How should universities manage intellectual property to acquire the necessary rights to the research results created by them? In addition, what should they do to ensure that their research results are exploited by industry or that they establish startups to contribute to industrial development? Universities need to manage intellectual property seamlessly from creation to exploitation. To do so, they should have a set of internal principles and basic concepts in place as an IP policy. The IP policy should be optimized in accordance with the university's social contribution principles and depending on its scale and the policy coverage of faculties and graduate schools. In general, therefore, the policy may vary from university to

university. However, there are also common elements. The following are points to be included:

(IP policy points)

(i) Ownership of inventions created on campus:

In 2002, Japan presented a fundamental concept of shifting invention ownership to universities (emphasizing the exploitation of inventions). In response to this concept, universities should draft a policy for acquiring invention ownership.

(ii) Invention notification:

If the right to obtain a patent belongs to the university, the university must have regulations in place to ensure that when creating an invention, the researcher promptly notifies the IP management office (IPMO) of the inventor, the invention description, and the research fund type to prevent losses from occurring in the case that another inventor of the same invention also files a patent. This is because Japan uses a patent system where the right to obtain a patent for a given invention lies with the first person to file a patent application for that invention (first-to-file system).

(iii) Determination of assumption of the right to obtain a patent:

No rights to inventions can be acquired without patent filing. However, patent filing requires a fee payment to the JPO and huge compensation to the representative patent attorney if used. A system is needed therefore that can systematically make an objective decision on whether the university should assume ownership of the right to obtain a patent. The university should have an organization and regulations in place to operate such a system. In this determination of assumption, emphasis should be placed not on the academic value of the potentially patented invention but on its commercialization prospect and market size, and the prediction of its patentability that the JPO will assess at a later date.

An IP policy is not completed when it is drafted up. The policy needs to be made familiar throughout the university. Although established organizationally by the university, the IP policy need not be followed by all the researchers at the university. Research styles vary among university researchers. Some devote themselves to basic research; others are enthusiastic about applied research. Generally, basic studies may often be published in articles, while applied studies may often lead to both article publication and patent filing. In addition, even if an invention created at the university is patented, it is meaningless unless a product or service using the patented invention is sufficiently marketable to be “given back” to society through business. Patent applications, if not potentially marketable, will just eat up money.

Thus, a strategy is needed for penetration of the IP policy. The IP policy should not only be posted on the website of the IPMO or the technology transfer promotion office. It is also important to seek the understanding of engineering and medical researchers who are potential inventors. Not all engineering and medical researchers

are interested in patent filing and technology transfer. It may be effective to identify researchers who could create successful examples, and help them actually create examples that could bring about a breakthrough in terms of penetration. Therefore, steady efforts must be made to achieve this by visiting laboratories individually, as well as holding explanatory meetings on campus.

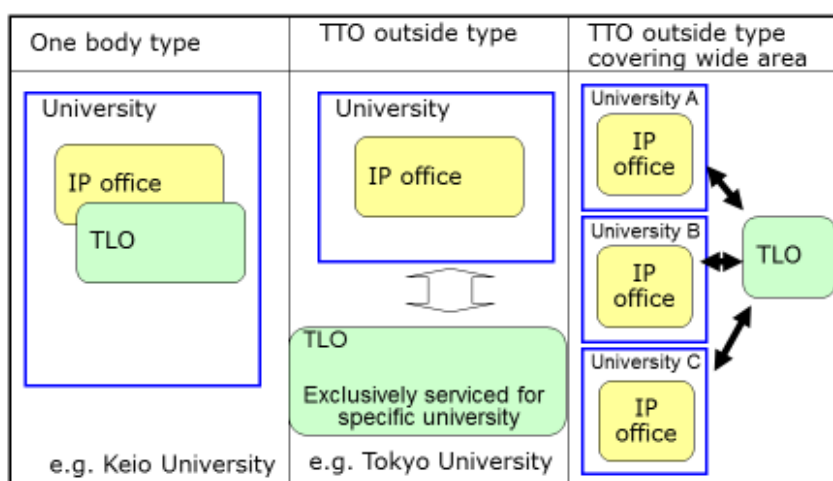
http://www.mext.go.jp/b_menu/shingi/gijyutu/gijyutu8/toushin/attach/1332043.htm [Japanese text]

4. IPMOs and TTOs (TLOs)

In 2002, MEXT notified universities of the November 2002 CST working group report to make it known to them that IP ownership was vested in universities.

In the following year, 2003, MEXT reviewed the plans submitted by universities for vesting IP ownership in them, the management and exploitation of created IPs, on-campus awareness raising, IP creation promotion initiatives, and cooperation with TTOs. MEXT then decided to support 34 universities for up to five years.

Various models for a patent prosecution and technology transfer from university



20

Under the plans, these universities established IPMOs (or IPOs) on campus for IP management. They also established TTOs (or technology licensing organizations, (TLOs)) as bodies for technology transfer activities to exploit patented inventions.

There are three forms of IPMO-TTO cooperation. The first is an integrated form of an IPO and a TTO. Examples can be found at Keio University, Nippon University, and the Tokyo Institute of Technology. The second is a form of one-to-one cooperation between a university and an extra-campus TTO. For example, Todai TLO, Ltd. exclusively handles the intellectual property of the University of Tokyo. Yamaguchi Technology Licensing Organization, Ltd. exclusively handles the intellectual property of Yamaguchi University.

The third is a form of one-to-many cooperation between an extra-campus TTO and multiple universities (wide-area TTO). For example, Kansai Technology

Licensing Organization Co., Ltd. handles the intellectual property of Kyoto University, Ritsumeikan University, etc., while Tohoku Techno Arch Co., Ltd. handles the intellectual property of Tohoku University, Iwate University, etc.

Each of the three types has developed with advantages and drawbacks, depending on the university scale and principles, as well as their historical backgrounds. Private universities, such as Keio University and Nippon University, originally had legal personhood and could establish the legal entity of a TTO on campus without problem. So such private universities adopted the integrated IPO-TTO form. On the other hand, national universities in Japan did not have legal personhood as of 2002. Thus, they had to set up TLOs—which are required to have legal personhood—outside of their campuses at that time. In 2004, national universities were then turned into legal entities. The TTO of the Tokyo Institute of Technology, for instance, has been integrated with its IPO. The integrated TTO is advantageous in that it is simple and can eliminate overlapping functions. However, it has a drawback in terms of personnel treatment. It cannot be flexible in terms of salary.

The TTO business focuses on (i) the discovery and evaluation of research results and (ii) licensing activities. The government has introduced support initiatives, including (i) the halving of patent examination and maintenance fees for TTOs and (ii) allowing national universities to invest in TTOs.

5. Cases of Student Invention

Undergraduate and graduate students generally have no employment relationship with their universities and are outside the scope of application of the employee invention provision of Article 35 of Japan's Patent Act. In the event of an invention made by a student, therefore, the right to obtain a patent for the invention belongs to the student, and the university will probably not be entitled, in advance, to take over that right from the student. In other words, it is problematic for the university to make a provision in its regulations stipulating in advance that the right to obtain patents for inventions made by students shall be vested in the university, and require students to abide by the provision.

As for inventions by undergraduate and graduate students, however, it is hardly conceivable that they would make inventions by themselves. In most cases, they may jointly make inventions under the direction of supervising researchers. In the case of a joint invention, a patent application should only be filed by all of the joint owners (Article 38 of the Patent Act). Given the exploitation of such inventions, it may be most appropriate first to put them under the centralized management of the university. In addition, it may not be wrong for the university to assume the rights to student inventions, considering that the students usually use the university's experimental equipment and other assets to make such inventions. Among others, the most acceptable way for inventors may be to file patent applications at the expense of the university, because huge expenses are needed to file a patent via a patent attorney.

In such cases, therefore, the joint student inventors and their supervisors should be encouraged to apply under joint signatures for transfer of the right to obtain a patent to the university. The university should review whether to take over the right, and if it decides to do so, it should file a patent application as an applicant at its own

expense. If the rights to the invention are later patented and exploited, bringing income to the university, the university should give a predetermined amount of return profit to the students and other eligible persons as a reasonable consideration.

6. IP Education

What is the significance of providing IP education at universities? The 2006 amendment to the Basic Act on Education specifies the giving back of research results to society as the third university mission. There may be several optional methods of giving back. One important option is through the exploitation of acquired intellectual property rights.

This option is not effective for all departments. It may work best primarily in medicine and secondarily in science and technology. In Japan, the students who can exploit IP knowledge on campus may be graduate and doctoral students because they are obviously researchers who might create inventions. Therefore, it is graduate and doctoral students who are the main targets of IP education at university. The following provides examples of IP lecture plans at a graduate school:

- (1) Lecture Plan of IP Management 1 (basic course of 14 sessions)
 - i. Intellectual property, and industry and society (Learning from recent IP case examples)
 - ii. Is the IP system meeting the needs of the times? (Pro-patent and anti-patent: history and global trends of patent systems)
 - iii. Articles and patents: patent features learned from familiar patent case examples
 - iv. Grace period and research notebooks: identification of true inventors
 - v. Assumption of the right to obtain a patent and reasonable consideration for employee invention
 - vi. Patent management (from patent filing to right maintenance), foreign patent filing, and exploitation of prior use rights
 - vii. Patent examination practice: exercise to judge easiness (inventive step) (patent examination simulation experience)
 - viii. Patent value assessment; patent literature investigation exercise (J-PlatPat, etc.)
 - ix. Business software-related inventions (patent requirements and recent trends)
 - x. Life science/pharmaceutical and patents (including research tool patents and patent term extension system)
 - xi. The US patent system features and operation examples (including US preliminary application)
 - xii. Patent systems in emerging China and other Asian countries
 - xiii. Patent infringement and defense against patent invalidation (patent infringement structure and conflict)
 - xiv. IP protection by copyright
- (2) Lecture Plan of IP Management 2 (applied course of 14 sessions)
 - i. Recovery from economic depression and university-industry collaboration

- (IP-based country; university mission)
- ii. University-industry collaboration and giving back of research results to society (exploitation of university research results)
- iii. Innovation creation; boundaries between patents, utility models, designs, trademarks, copyright, and know-how
- iv. Joint research (part 1: joint research structure and handling of research results)
 - v. Joint research (part 2: examples of agreement from negotiation to execution)
- vi. Structure of license agreement from negotiation to execution
- vii. International negotiations and IP
- viii. Trade secret management and freedom of career choice
- ix. Patents and the Antimonopoly Act (negotiation skills for joint research and licensing)
 - x. 5Ws and 1H of technical agreement
- xi. Patent and technical standards, patent pools (focusing on examples of MPEG, etc.)
- xii. Patent practice and exhaustion (taking the printer ink tank case as an example)
- xiii. Material transfer agreement (MTA) and security trade control
- xiv. Conflict of interests (COI) and research ethics

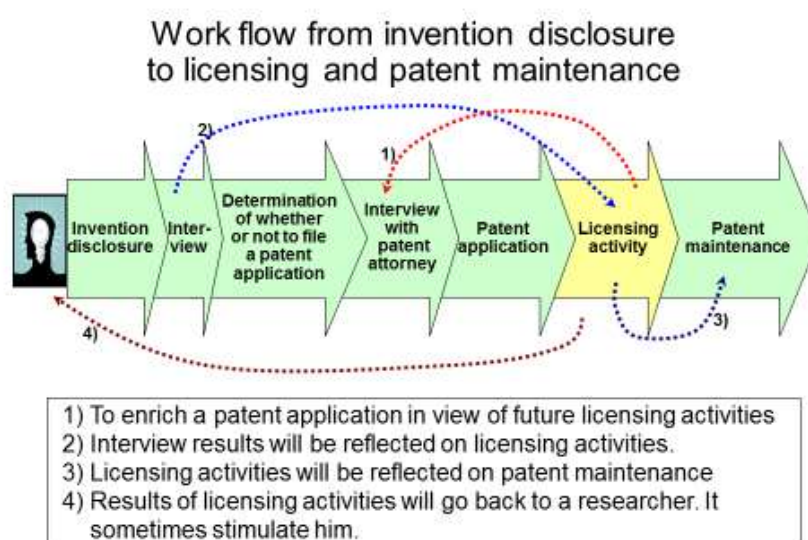
3. From Invention Discovery to Technology Transfer

1. Entire Flow

The chart below shows the entire flow of IP management operations in conformity with IP management policy and regulations.

(1) Invention disclosure:

This means that when creating an invention, a university researcher submits a notice of invention to the university's IPMO. The notice of invention should consist of Form A, which includes, for example, bibliographic information and fund sources; Form B, which describes the invention; and Form C, pertaining to exploitability. Form A should contain the name of the person who submits the notice of the invention; the title of the invention; a list of the names and affiliations of all the inventors (including those inside and outside the university); whether conference presentations or other publications are planned; and research fund sources (to check for Bayh-Dole or joint research contracts). Form B should contain the technical field of the invention, the prior art (including article titles and patent document numbers), matters and problems of the prior art, the concrete constitution of the invention, and the advantageous effect of the invention. Finally, Form C should contain the field of industry in which the invention is to be practiced, the names of companies likely to become interested in putting the invention to practical use and the reasons therefor, the market size (the scale of economic impact of the invention), and technical problems expected before commercialization and methods to solve said problems (including the necessary period and research costs).



31

(2) Interview of the inventor:

Upon receipt of the notice of invention mentioned above, a technical staff

member of the IPMO promptly interviews the inventor to obtain useful information for future technology transfer activities, as well as to clarify unclear points in the statement. If this technical staff member is appointed to take charge not only of patent application procedures but also of technology transfer, operational overlaps can be minimized in the work flow shown above. In addition, it is effective to raise the awareness of the technical staff to ensure:

- that they interview the inventor in the context of future technology transfer activities; and
- that the details of the interview with the inventor are stored and preserved for reference at any time during future technology transfer activities.

(3) Determination of whether to file a patent application:

The IPMO decides in council whether the university will take over the invention specified in the notice of invention to file a patent application. The technology transfer staff member who interviewed the inventor in (ii) above shall explain the matter at the council meeting. For details, see 3.3 “Patent Filing.”

(4) Interview with the inventor by the patent attorney:

After the university has decided to apply for a patent for the invention and has assumed the right to obtain a patent to it, it should promptly appoint the most appropriate external patent attorney to draft a specification and properly acquire the rights to the invention. To that end, it is important to have agreements with patent attorneys in various fields to be able to cover ordinarily the research fields in which the university researchers are engaged. The appointed patent attorney shall promptly interview the inventor. If there are in-house experts available with skills equivalent to those of a patent attorney, the university can reduce expenditures by filing an application directly with the JPO without relying on an external patent attorney.

(5) Patent filing:

In the case of hiring an external patent attorney, the patent attorney office files patent applications on behalf of the university. A copy of the filing documents should be retained at the IPMO.

(6) Licensing activity:

After the completion of patent filing, promptly launch technology transfer activities. For details, see 3.5.

(7) Patent application maintenance

Ensure proper patent application maintenance. Maintain the patent application while the invention is licensable, but when it becomes no longer licensable, promptly abandon the application to prevent further expenditures. For details, see 3.6.

2. Invention Discovery

Researchers have sometimes made important inventions in terms of the patent system, even without realizing they have done so. When interviewing researchers who have contributed many articles but have not submitted notices of invention, it may be revealed that they have actually made inventions. Such discovery of inventions by researchers that had previously remained obscure, through hearings from them, is called “invention discovery.”

Generally, only some, but not all discovered inventions, are suitable for patent application at the JPO. Grasping the entire stock of created inventions may lead to discovering inventions for which a patent should be applied.

As mentioned above, not all university researchers make inventions, and they are not obligated to do so. Researchers can be divided into two types. Researchers who make many inventions tend to be good at repeatedly gaining competitive funds and corporate research funds, thereby making further inventions. Meanwhile, there are many researchers who do not engage in invention. Young researchers have yet to fall into either type. Therefore, it should be identified which type they will become by interviewing them about invention discovery. A list of inventors prepared through such discovery work can become an important database for IPMOs and TTOs. Based on this list, the technology transfer staff member periodically interviews and hears from inventors, leading to more effective invention discovery.

3. Patent Filing

Patent filing requires huge expenses. The expenses can be divided into (i) procedural expenses paid to the JPO (“JPO procedural expenses”) and (ii) compensation for the representative patent attorney (“patent attorney expenses”). As JPO procedural expenses, a filing fee of 14,000 yen, and an examination fee of around 140,000 yen to be paid within three years of filing, are required on an interim basis. Upon receipt of a patent grant, a registration fee of about 3,000 yen should be paid to obtain a patent. Meanwhile, patent attorney expenses consist mainly of around 200,000 yen for drafting a specification and the scope of patent claims necessary for filing (an amount which may vary depending on the number of pages), and several tens of thousands of yen for a rebuttal argument and amendment preparation if the examiner issues a notification of reasons for refusal after examination.

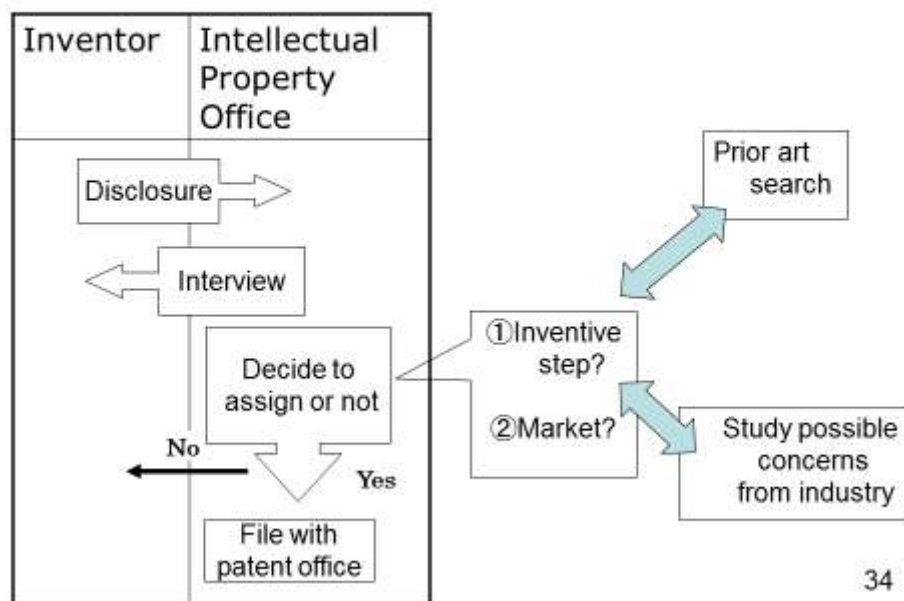
The JPO procedural expenses are essential for patent filing, but patent attorney expenses will not need to be paid if the university prepares a specification and files an application on its own. As for the JPO procedural expenses, universities and approved TLOs are eligible for halved examination fees and halved annual patent fees (for the first year to the 10th year), which are an incentive measure taken by the government. Generally, therefore, the JPO procedural expenses are less expensive than patent attorney expenses. If patent attorney expenses are saved, the resulting effects will be enormous. However, patents will become valuable only when they are exploited (commercialized). Technology transfer may not occur even with an excellent invention if the scope of rights to it is too narrow or if it is easy to avoid the scope. Thus, if the university does not hire a patent attorney, it needs to keep equivalent internal experts on staff. Patent attorneys are expected to draft specifications and scopes of patent claims, taking future exploitation into account. To

that end, it is also important to hire patent attorneys with rich experience in the relevant technical field, such as electricity, information, machinery, chemistry, life science, and medical care.

Despite preferential treatments in place for the JPO procedural expenses, universities and approved TLOs still have to pay large sums to patent attorneys. Therefore, patent filing costs are huge, and it is necessary to select from among inventions for filing applications and adjust the number of patent applications within the budget.

The following provides the procedure for selecting inventions for patent filing. Upon receipt of an invention disclosure/proposal from an inventor, the IPMO dispatches an expert to the inventor to conduct a hearing on the inventor, a description of the invention (prior art, problems and their solutions, and operation and effect), a prior art list, fields of practice, candidate licensees, the market size, and problems related to practical use. Based on such information, the IPMO conducts a prior art search and market research. If the prior art search reveals that an almost identical invention is already publicly known, the patent filing will be canceled. However, the university files an application if the invention can be differentiated from the prior art and the market is expected to be large when the invention is commercialized. In other words, the university takes over the right to obtain the patent from the inventor and asks for the drafting of a patent applicant's specification for filing with the JPO.

Flow of patent applications



34

4. Foreign Patent Filing

Under the patent system, a patent may be granted in each country where a patent application is filed. This means that the scope of patent right protection is limited to the country where the patent is applied for. It is desirable, therefore, to file patent applications in countries where patented inventions can be expected to be practiced through business operations. However, it is necessary to select carefully the countries

in which to file considering future profits, since patent filing and right securing in a single country may cost around 1 million yen, although this will vary from country to country.

The following provides the procedure for foreign patent filing:

(1) PCT route

For inventions created at universities in Japan, if it is worth applying for a patent, it is generally applied for with the JPO first (first country application). Then, if technology transfer gives rise to expectations that a certain company may use the patented invention overseas, a Patent Collaboration Treaty (PCT) application should be filed within one year from the date of the first country application. For PCT application filing, submit filing documents in a PCT-designated form to the JPO, one of the PCT receiving offices. The big advantage of PCT application is being able to select foreign countries in which to apply for a patent within two-and-a-half years from the date of the first country application. If the technology licensee of the university's patented invention is determined within the two-and-a-half-year time limit, national phase patents should be filed in selected foreign countries at the expense of that company. This is a desirable foreign application pattern. If the two-and-a-half-year time limit expires before agreement with the potential technology licensee is in sight, however, it is advisable to give up all the nationalization applications or limit the nationalization only to Japan if there are bright prospects for the patented invention in the future in Japan.

Foreign filing as above requires huge expenses, including translation. In Japan, the Japan Science and Technology Agency (JST) provides universities with expense loan support, including attorney payment, for filing PCT applications. To have its patented invention selected for this support, the university needs to ensure the likelihood of licensing the invention, such as by concluding a licensing agreement with a company. If it obtains a licensing income, the university will then repay the loan with that income in half installments.

(2) Paris Convention route

This route, although it may not be often used, means filing an application with a priority right directly with a necessary country within one year from the first country application that serves as the basis for the claim of priority. This route can help save PCT application expenses. As a disadvantage, however, the choice of countries in which to file for patent protection should be made within one year from the first country application, and upon the decisions being made, huge expenses including translation will need to be paid.

5. Licensing Activities

Licensing activities are the most important component of universities' technology transfer activities. Universities do not use and commercialize their inventions on their own.^(Note 1) Thus, universities have two options to ensure that their inventions are exploited in ways that contribute to society: (i) licensing patents for them to existing companies or (ii) having university inventors set up startups and exploit them. If the possibility of both options (i) and (ii) arises, choose the one that is likely to have more

social impact or a greater economic ripple effect through the exploitation of the patented invention.

(Note 1) Universities may use but not commercialize inventions in the course of research.

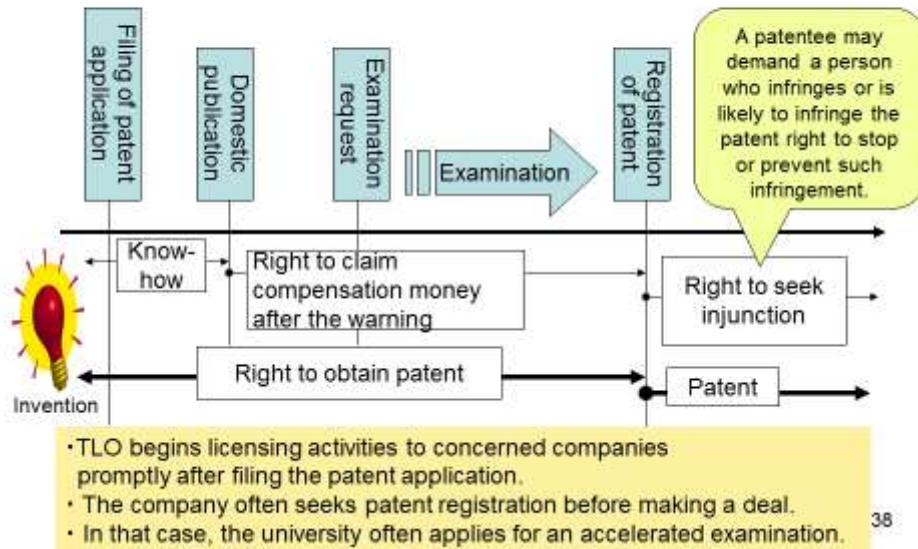
At what timing should licensing activities, of which TTO experts take charge, start? The activities should begin soon after the completion of the patent filing. There is a timing for licensing inventions. It is said that patented inventions are licensed mostly within three years from patent filing.

Inventions are kept confidential within one-and-a-half years from patent filing. If the university has to disclose its confidential invention to a technology licensee candidate, according to the textbook approach, the university should conclude a non-disclosure agreement (NDA) with the candidate before explaining and sounding out the candidate for licensing. However, if the university urges the licensee candidate to sign an NDA when the candidate has little interest in gaining a license, it will often discourage the candidate from proceeding with negotiations. It is necessary therefore to handle an NDA, paying attention to the fact that owning the duty of confidentiality regarding the disclosure will become burdensome to the candidate. Attention should also be paid to the fact that if the candidate already possesses said duty before disclosure, a complication will arise upon disclosure: the candidate cannot claim possession of the secrecy without proving that it has independently held the secrecy.

Therefore, the university often adopts a method of introducing its new invention, even if kept secret, using only documents in the public domain. On top of that, it is a good policy for the university to proceed to conclude an NDA only if the candidate shows some interest in the invention, with technology transfer seeming more likely.

The licensee will, in most cases, make it a condition for the NDA that the university's invention be patented. The university will then immediately request the JPO for an accelerated or super-accelerated examination. The JPO shall accept requests for accelerated examination from universities, public research institutes and SMEs without additional charge. In the accelerated examination, the final decision will be sent within an average of two months from the date of filing the request. If the decision is made to grant a patent, it will lead to the conclusion of a licensing agreement. If the decision is made to refuse the application, the licensing will end in failure.

When do you request patent examination? Do you need accelerated examination?



6. Patent Maintenance

Patent filing is the start, not the finish. Patent filing is followed by necessary procedures to check the possibility of domestic priority application and PCT or other international applications in the first year, nationalization/regionalization of PCT applications in two-and-a-half-years, and the expiration of the examination request in three years; to respond following an examination request; and to pay the patent registration and maintenance fees. It is also necessary to judge properly whether to maintain the patent application and patent rights whenever expenses are incurred. Patents that are less exploitable or not profitable even if exploited should be promptly abandoned, and the expenses saved should be appropriated to filing new patent applications.

The following provides points to keep in mind:

(1) The first year after filing (Check 2 in the figure):

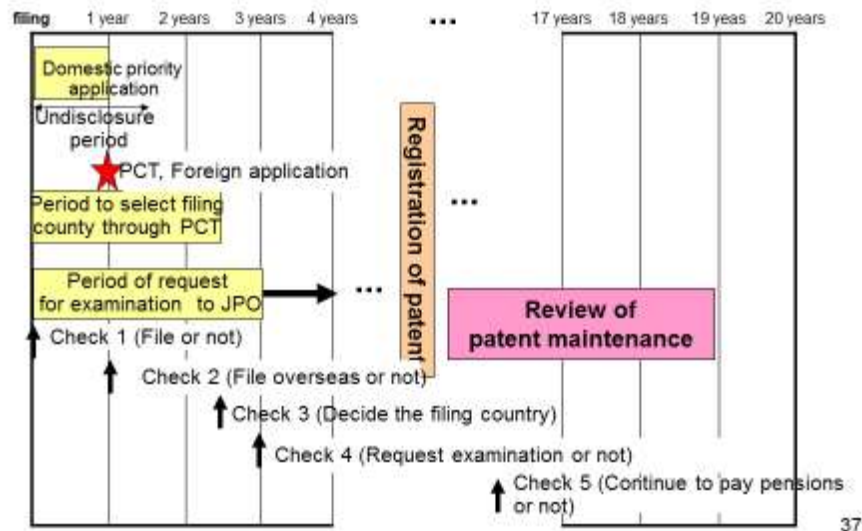
Check whether to file a domestic priority or foreign applications. If useful embodiments are added or applied technologies are invented within one year after filing, the applicant can file a comprehensive patent application including these additional inventions. This is domestic priority application. Of course, the filing date for these additions will be the date of domestic priority application, not the filing date of the invention on which they are based. This domestic priority application is also very costly, although less so than the initial application. The applicant needs to decide carefully based on the status of technology transfer of the patented invention.

The applicant should also check whether to file foreign applications. PCT applications may be filed if upon the technology transfer activities after filing the company finds that the invention may be highly exploitable in overseas

operations, leading to joint research or a licensing agreement. As the PCT and following national phase applications are highly costly, it is difficult for universities to pay these costs by themselves. They should, therefore, have the companies exploiting the inventions for overseas operations bear the costs, or should apply for the national support system (or a foreign patent application support system). To receive the country's support, it is also important to have clear prospects for overseas technology transfer in advance.

- (2) Thirty months (two-and-a-half years) after filing (Check 3 in the figure):
If the company is to operate overseas with the invention after PCT application, applications should be filed in countries in which it is deemed necessary to exercise rights in the future, at the expense of the company or using the national support system. Generally, markets in the US, Europe, and China are large. However, do not file foreign applications when it is not anticipated that the company will exploit the patent overseas.
- (3) Three years after filing (Check 4 in the figure):
In Japan, the time limit for a request for examination is three years. Request an examination if the invention for which the patent is applied shows until this time the prospect for technology transfer to or joint research with the company. Otherwise, the applicant should not make such a request. If the applicant does not request an examination, the patent application will be deemed to have been withdrawn.
- (4) After patent examination/registration (Check 5 in the figure):
If it is found that the licensee company, which was originally likely to receive technology licensing, has later decided not to exploit the patented invention because of its business policy change, payment of patent maintenance should be promptly stopped to prevent further loss.

Timing for review after patent filing Check the possibility of working this patent application



37

7. Infringement Discovery and Warning/Litigation

Cases sometimes occur where an enterprise has already used the patented invention of a university. The company and the university may have accidentally made the same invention separately. Alternatively, the company may have read an article of the university's research results or the Japanese Kokai Publication of the patent application. If, even in such cases, it is evident that the company is using the university's patented invention (conflicting with the scope of rights for the patent), the company could be infringing the university's patent. The university can assert patent infringement against the company if patent rights are granted for the invention.

However, infringement is hard to prove. In particular, universities and TTOs in Japan do not often have the experts on staff or the budget to disassemble, investigate and analyze infringed products. They cannot, therefore, collect evidence or have recourse to the courts even if they warn the suspected infringers. If the infringers ignore such warnings, it is difficult for the universities or TTOs to probe further into their suspicions.

On the other hand, many large companies can employ experts in analysis and examination of infringed products, or have sufficient budget to outsource such analysis and examination. Accordingly, they have considerable bargaining power so that they can often settle patent litigation, and in turn, obtain compensation for damage or licensing fees.

In the US, universities have off-campus TTOs that, like large Japanese companies, employ expert analysts and have a budget for using external services. If investigation reveals infringement of their patents, the universities can negotiate with the infringers, without ruling out litigation. In most cases, the universities reach settlement during negotiation. Having such an anti-infringement system in place may

be one reason why US universities obtain a substantially larger license income than their Japanese counterparts. For Japanese universities, it is a challenge for the future to determine whether to equip their off-campus TTOs with this function.

8. Patent Invalidation Trials

If the university makes a licensing negotiation proposal to a company suspected of using the university's patented invention, the counterparty company may, in turn, file a trial for invalidation of patent. The counterparty company's claim for patent invalidation would come from the background that the company is using the patented technology or has a strong plan to use it in the future. This means that the university's patented technology is of extremely high value in terms of commercialization. Let us introduce an example. A university proposed to a company a reasonable licensing or patent assignment for the university's patented technology. However, the company claimed for invalidation of the university's patent, saying that it would file an appeal with the high court if it lost the JPO trial. Although the patent invalidation application and the subsequent dispute would consume considerable cost and time, the company insisted that it wanted to have the university's patent invalidated, even if it meant shouldering such burden.

As the investigation proceeded, it was found that the company claimed for patent invalidation on the grounds of a journal article contributed by the university's inventor that made the invention known to the public, and the patent application was filed after that, without filing for exception to loss of novelty. In other words, the company insisted, the university's patented invention could be easily invented based on the article published by the inventor.

At that time, the university had just put an on-campus IP management system in place and not all of its researchers were fully familiarized with the patent filing system. The company strategically took advantage of that systematical imperfection. As a result, the patented invention was found to have been easily inventible based on the inventor's journal article, and the patent was invalidated. This experience taught the university about the importance of inventors filing patent applications before article publication or, in the worst case, while applying for an exception to loss of novelty within a six-month grace period after the article publication. From the action taken by the counterparty company, the university also learned the actual pattern of corporate behavior in which companies use university-originated technologies but try to find some way to have the patents in them invalidated, instead of being licensed.

This example may provide a useful lesson to universities that have just started intellectual property management, with their researchers starting to become familiar with the mechanism for the IP system.

9. License Examples

Orange 2

License example 1:

In 2001, then Professor Masato Nakajima and another member of Keio University School of Science and Technology, created an invention for a handwriting-like character font generation system. The university took over the right to obtain a patent

for the invention and then filed a patent application via the representative patent attorney (Application No. 2001-380597). Since the inventor, Professor Nakajima, was among the researchers at the School of Science and Technology who were the most intellectual property-conscious and eager to transfer technology, the technology transfer staff could successfully proceed with the licensing activities. Then, with the prospects for licensing in sight, the university requested examination of said application and an accelerated examination. Although the university received a notification of reasons for rejection from the JPO Commissioner, it submitted a rebuttal argument and amendment, and consequently, about one-and-a-half years after filing, the application was registered in the patent registry in June 2003 (Patent No. 3438009). At that time, the university had to wait quite a long time for JPO examination but felt that the accelerated examination system gave the opportunity for the applicant to promptly obtain a patent when necessary.

The licensed invention converts characters entered in a PC into personalized fonts that resemble the user's handwriting, and enables the computer monitor display or printout of text written in such fonts. The invention is a breakthrough in that it extracts the user's handwriting features from as few handwritten characters as possible to decrease the user's burden of writing, and, based thereon, generates character fonts of any character type that reflect the user's handwriting features. As shown below, the invention was incorporated into PC software, which became widely available on the market.

<https://www.est.co.jp/orenji/index.html> [Japanese text]

License Example 1
Generative System of Handwriting Fonts
Inventors: Former Prof. Nakajima et al.

Turn your handwriting into a font!

Orange 2 allows you to turn your handwriting into a font in a very simple way, giving you the creative freedom of customizing your font collection for letters, mailing labels, name cards, web pages, diaries, or essays.



Windows CD-ROM for 98/Me/97/2000/NT4.0

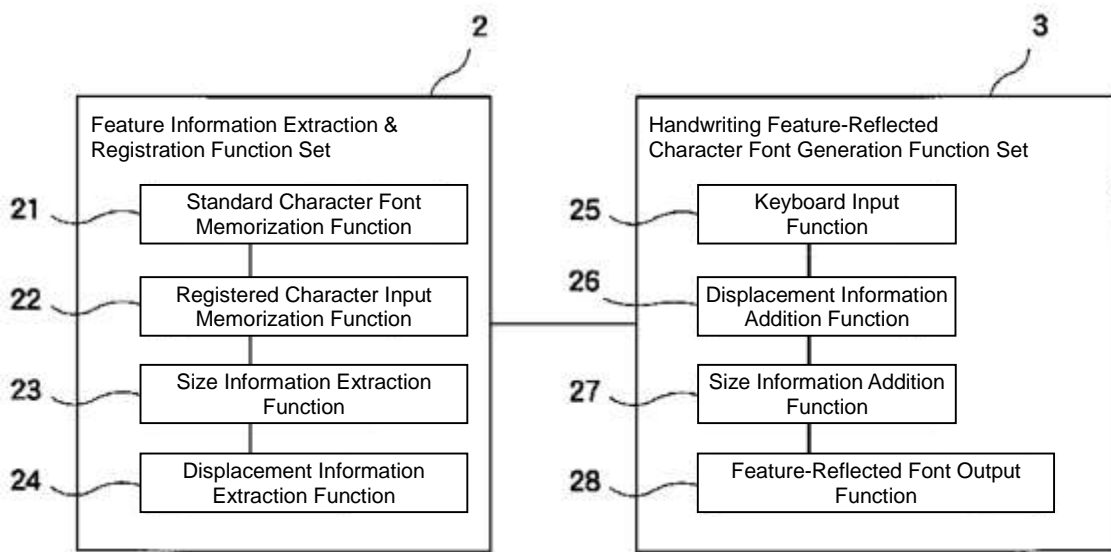
27

The following describes the functions and operations of the patent-registered invention using the following functional diagram.

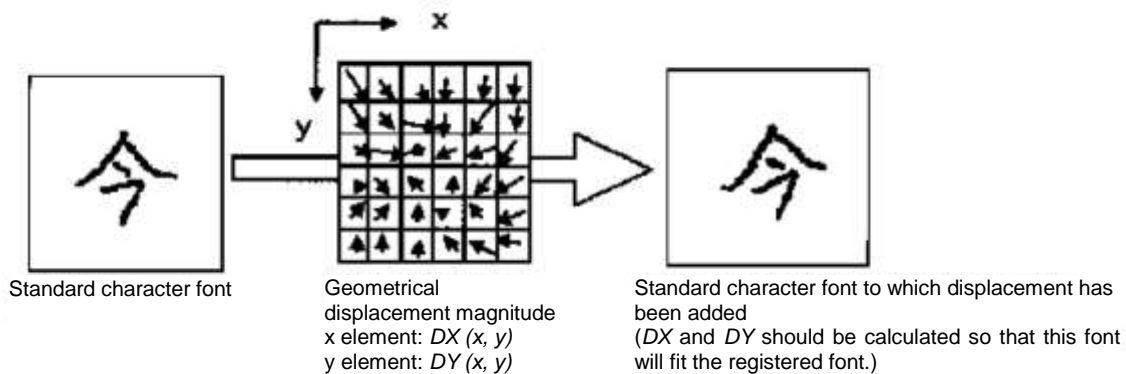
- (1) Steps to register the user's handwriting feature information on a PC
 - (i) In Feature Information Extraction & Registration Function Set 2, use Standard

Character Font Memorization Function 21 to have the PC memorize a set of pen *kaishotai* block style fonts from a commercial standard font package.

- (ii) Handwrite a composition of 100 to 200 characters in *kaishotai* block style on boxed manuscript paper, adding your handwriting features thereon. On top of that, use Registered Character Input Memorization Function 22 to memorize the individual handwritten characters as image data in the PC.
- (iii) Then use Size Information Extraction Function 23 to acquire character size information as your first handwriting feature information. Character size information is defined as the average of all the handwritten characters by rates determined per input image of the vertical length of the box containing a character on the paper to the long-side length of the rectangle circumscribed to that character.



- (iv) Then use Displacement Information Extraction Function 24 to analyze character geometrical displacement information as your second handwriting feature information. After simultaneously standardizing the sizes of the standard font character and handwritten character of, for example, the kanji “今” (meaning “now”) as shown in the diagram below, compartmentalize both characters, for instance, in a six-by-six grid comprising 36 small squares. In each square, search for correspondences in position between the standard font character and the handwritten character. In other words, determine the direction and magnitude of displacement in each square area of the handwritten character to find how it is displaced from the standard font. Take the averages of the displacement directions and magnitudes of the squares as your handwriting feature information.



(2) Steps to output character fonts that reflect the user's handwriting feature information

The following describes how to print out from the PC characters in fonts that reflect the user's handwriting feature information (poorly handwritten characters).

- (i) First enter a composition you want to print out, using the PC keyboard.
- (ii) Next extract a character corresponding to the keyboard-input character code from pen *kaishotai* block style fonts memorized in advance using the Standard Character Font Memorization Function.
- (iii) Use Displacement Information Addition Function 26 to add geometrical displacement magnitude to the extracted standard pen *kaishotai* block style character. Moreover, use Size Information Addition Function 27 to adjust the size to obtain the character font to be printed out. For this process, the output of Displacement Information Extraction Function 24 is entered in Displacement Information Addition Function 26, and the output of Size Information Extraction Function 23 in Size Information Addition Function 27.
- (iv) Finally, output this character font to the printer.

In addition to the functions and operations of the patented invention as described above, the following provides a description of the claims as the scope of patent rights for this invention for reference. The description shows that the functions and operations therein are generically conceptualized in comparison to the above to ensure a broad range of rights.

(Reference)

[Claims]

[Claim 1] A handwriting-like character font generation system featuring:

a displacement information extraction means for extracting statistical information on displacement magnitudes that are determined in each position within an image by comparing a first memory for memorizing m (m : natural number) standard character fonts to a second memory for memorizing n (n : natural number, $n < m$) image-captured character fonts, and the captured character fonts memorized in said second memory to the corresponding standard character fonts memorized in said first memory; and

a displacement information addition means for adjusting and outputting the

character font memorized in said first memory in accordance with the output of said displacement information extraction means.

License example 2:

As another licensing example is an invention in the field of health care. Masataka Kuwana, then instructor at Keio University School of Medicine, invented a diagnostic agent for scleroderma. The university decided to file a patent application for this invention while taking over the right to obtain a patent for it and hiring an external representative patent attorney to apply for the patent (December 2001). After that, the university found a licensee with prospects for practical application of the invention in sight, and in October 2002, requested examination of said application and accelerated examination. One month after the request for examination, a notification of reasons for rejection arrived. In response to the notification, the university underwent an oral examination and then submitted a rebuttal argument and amendment. In August 2003, the invention was patent-registered (Patent No. 3455782), one year and eight months after the patent filing.

Scleroderma, the disease for which the invention was created, affects an estimated 30,000 people in Japan, a number that is not excessively high but not insignificant. Conventionally, this disease had been difficult to diagnose. However, the diagnostic method developed by the inventor, Dr. Kuwana, has enabled diagnosis of the disease with significantly high accuracy. Through joint development with the licensee, the invention was put to practical application as an in vitro diagnostic anti-RNA polymerase III antibody measurement kit. The product received market approval from the Ministry of Health, Labour and Welfare (MHLW) in December 2009 and health insurance coverage in May 2010. (<http://www.mbl.co.jp/ir/press/2010/0520.html> [Japanese text]).

While, in the case of an engineering patent, the licensee can determine at its discretion when to put an invention to practical use, it should be kept in mind that pharmaceutical inventions, like this example, can be put to practical use only when receiving MHLW market approval and health insurance coverage. Even though the bar for approval may be quite low for in vitro diagnostics in comparison to oral drugs, the measurement kit took almost 10 years from patent filing to receipt of insurance coverage. For reference, note that this kit received approval from the Food and Drug Administration (FDA) in the US in 2006, three years earlier than in Japan.

Licensing example 2: New in vitro diagnostic anti-RNA polymerase III antibody measurement kit against autoimmune disease systemic sclerosis (SSc)

Invented by Mr. Masataka Kuwana, former professor of Keio University School of Medicine

2001 Patent application filed
2003 Patent-registered in Japan
After that, as an in vitro diagnostic,
2006 Approved by FDA
2007 Patent-registered in the US
December 2009 Given MHLW marketing approval
May 2010 Given health insurance coverage and put on the market

[Product Overview]

Product name: MESACUP anti-RNA Polymerase III Test

Measurement purpose: To measure anti-RNA polymerase III antibodies (autoantibodies produced specifically in SSc) in serum

Manufacturer's suggested retail price: 115,000 yen per kit (96 tests)

<http://www.mbl.co.jp/ir/press/2010/0520.html>



Licensing Example 3:

The third licensing example relates to an invention in the field of robotics. Professor Kouhei Ohnishi and two others from Keio University's Faculty of Science and Technology created an invention in the field of next-generation robots. The name of the invention for which the patent application was filed is "a position/force controller," but the representative embodiment is a robot hand with haptic sensation. The right to obtain the patent succeeded to the university from the inventors, so the university filed a patent application (JP2013-194704) on September 2013 via an external patent attorney. A year after that, the university filed a PCT application (PCT/JP2014/073083). According to the outcome of an international PCT search, there were no documents of particular relevance as prior art, so only a document indicating the general state of the art (Document A) was cited. In other words, the opinion of the Japan Patent Office (JPO) examiner dealing with the application was that there was no prior art denying the novelty or existence of an inventive step in the claimed invention. In the course of joint research with a major plant manufacturer after the patent application was filed, the invention was commercialized in the manufacturer's field of business and proceeded to be licensed. The claimed invention could conceivably be deployed in a diverse array of fields, so the manufacturer has formed a consortium with companies in other fields and is pursuing business development.

The following provides an introduction to the technology in the claimed invention.

When humans touch an object, they sense the hardness or softness of that object and adjust the force they use accordingly when touching it or grasping it. As a result, they can grasp an object without breaking it or dropping it. Haptic sensation is the sensation of hardness or softness that is felt when doing so. It would be fair to say that haptic sensation (= touch) is one of the five human senses (sight, hearing, touch, taste, smell). Professor Ohnishi was the first person in the world to commercialize a robot hand that can transmit haptic sensation information and be operated via telecommunications. Professor Ohnishi created a major sensation when he exhibited the "Haptic-sensitive Robot Hand" at CEATEC JAPAN 2015, which was held at Makuhari Messe on October 7-10, 2015. <http://www.ceatec.com/news/ja-webmagazine/ja-024>

At CEATEC, he demonstrated how the master-slave robot hand can be operated by remote control to grasp a potato chip without breaking it. On the master side, a human thumb and forefinger perform the action of grasping something, and the information about this action is transmitted to the remotely located slave side. On the slave side, the robot hand grasps the potato chip based on the information transmitted. If it grasps it too strongly, the chip will bend, but if it does not grasp it strongly enough, the chip will fall out of the robot hand. The slave side acquires haptic sensation information about the strength or weakness of the pressure and transmits it to the master side. The information transmitted is converted into a haptic sensation that the human thumb and forefinger on the master side can feel, enabling the human operator to adjust the pressure and ensure that the robot hand grasps the potato chip without breaking it. On the other hand, when the haptic sensation function is switched off and the robot hand is operated using positional information alone, the potato chip breaks, no matter how carefully the operator tries to grasp it. As such, this invention brought

into sharp focus the function of haptic sensation.

The author also noted that the scale of the haptic information can be freely adjusted. Along with the other senses, the sense of touch declines as we age, so with Japan facing an increase in its elderly population, the technology in this invention could be used to compensate for deficiencies in this area. Just like we have spectacles for our eyes and hearing aids for our ears, we could use a haptic sensation robot for our hands. For example, doubling the intensity of the haptic information returned to the operator would mean that they would be able to handle objects even if their sense of touch had dulled, and there would be no problem even if they handled a delicate object roughly. In other words, it would be possible to prevent objects being broken or dropped.

This would seem to be a promising technology that has tremendous potential for application in all kinds of fields, including disaster relief and recovery, medical care and welfare, and civil engineering, not to mention industry.

Haptics Explores The World of IoA



～The Invention and Deployment of a Fresh Method of Transmitting Haptic Sensation～



Haptic-sensitive Hand

By remote control, this master-slave robot hand can grasp a remotely located potato without breaking it.

Conventional technique

- Transmits positional information in one direction only
- Cannot transmit force, so cannot judge the haptic sensation

主
から
ない

Master

Position signal

Does not feel the object..
Breaks it...

Slave

Proposed technique

- Transmits haptic sensation information in both directions
- Locally senses haptic sensation from remote objects

感
じる

Master

Haptic sensation signal

Can feel the object!
Can grasp the object without breaking it!

Slave

Applying this technology would make it easy to create robots that work flexibly in partnership with humans.

We are aiming to open up the world of IoA (Internet of Actions), in which actions themselves are turned into content that can be downloaded and reproduced as needed.

CEATEC JAPAN 2015 慶應

Keio University Haptics
Research Center

センター haptics-c.keio.ac.jp

For reference, the description of the claimed invention in the scope of claim (in the PCT application) and a representative drawing to aid understanding of the description are provided below.

Scope of Claim [Claim 1]

A position/force controller which is provided with:

a position detection means for detecting information relating to a position based on the effect of an actuator;

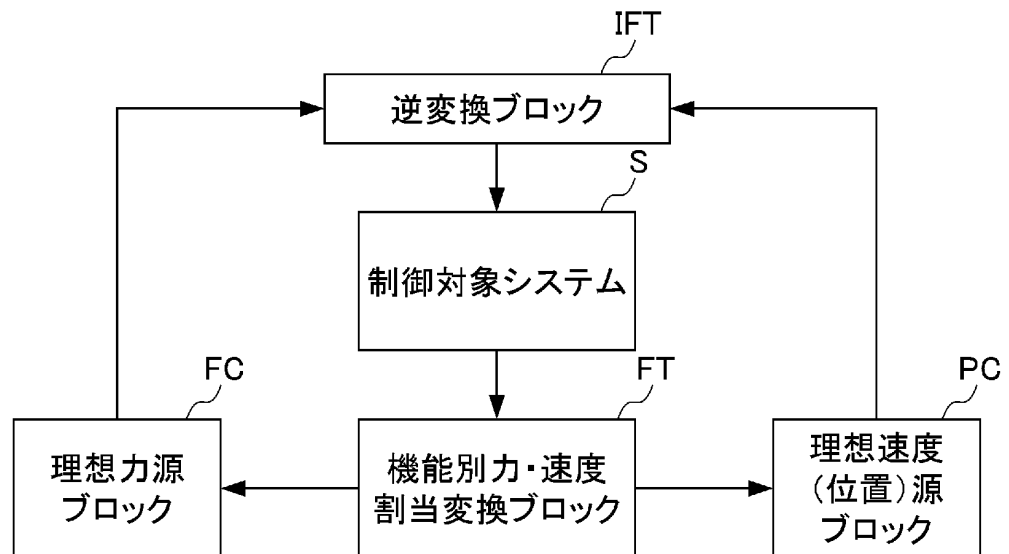
a function-dependent force/speed distribution conversion means for performing conversion by distributing control energy to speed or positional energy and force energy in response to functions realized on the basis of speed (position) and force information corresponding to the information relating to the position and on the basis of information serving as a reference for control;

a position control amount calculation means for calculating the control amount for speed or position on the basis of the speed or positional energy;

a force control amount calculation means for calculating the force control amount on the basis of the force energy;

and an integration means for integrating the speed or position control amount and the force control amount and performing a reverse conversion on the speed or position control amount and the force control amount to return the output to the actuator, to determine the input to the actuator;

and which, with these elements, makes it possible to control the speed or positional energy and force energy independently.



FC Ideal force source block

FT Function-dependent force/speed distribution conversion block

IFT Reverse conversion block

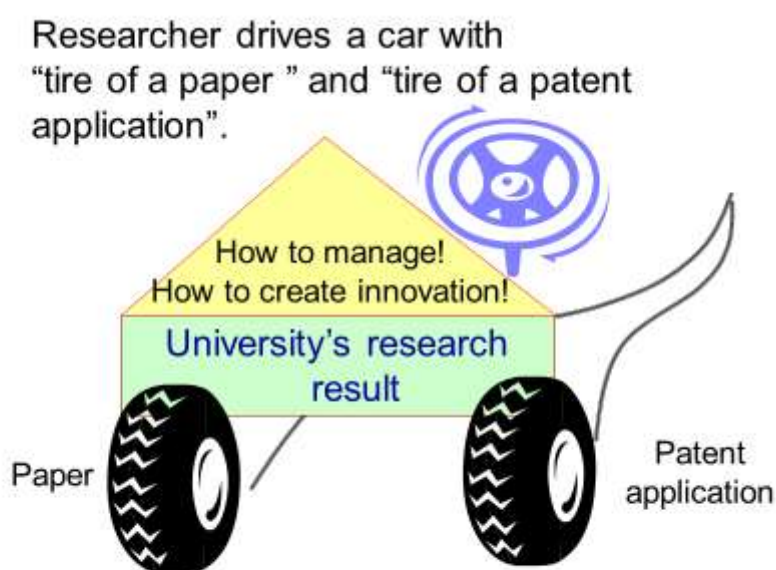
PC Ideal speed (position) source block

S System to be controlled

4. Characteristics of University Patents, and Domestic and Foreign Patent Acquisition Practices

1. Paper and Patent — Taking iPS Cell Invention as an Example —

Before universities set up an on-campus IP management office, all university researchers had to consider was writing articles. Since universities have been expected to give back research results to society, however, the need has arisen for university researchers to consider both article writing and patent filing. Researchers have been required to provide society with research results, taking both article writing and patent filing into consideration. However, this is not the case for all researchers but only for some medical, scientific, engineering and pharmaceutical researchers, as described in 3.2 “Invention Discovery.”

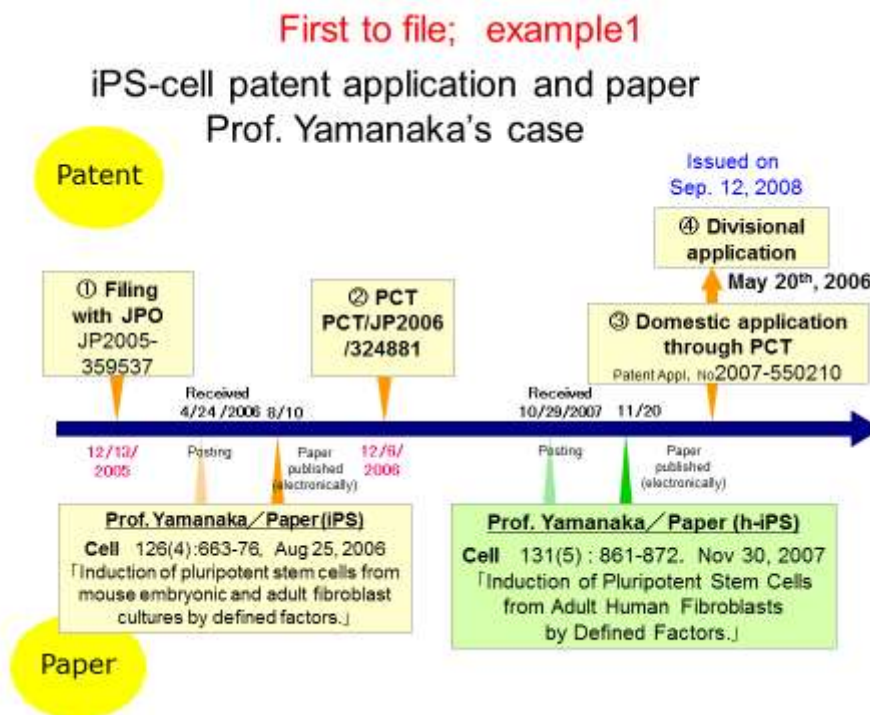


13

Submission of an article and patent application involves the problem of order of submission. The patent system provides strict criteria, including the first-to-file principle, and novelty & inventive step requirements. If the invention does not fulfill the criteria, a patent will not be granted. In 3.8 “Patent Invalidation Trials,” for example, a case was presented where the patent, after being granted, to the university-originated invention was invalidated in the end because of an article published by the inventor. As a core strategy, therefore, inventors should in principle file a patent application before public disclosure of a corresponding article (it is, however, acceptable to file after article contribution). However, if the university deems it necessary to file a patent application despite the inventor not being able to follow this strategy for any reason, the inventor should file a patent application using the grace period system described in 4.2. (for details, see the following paragraph).

The following provides a case of iPS cell invention in which Kyoto University

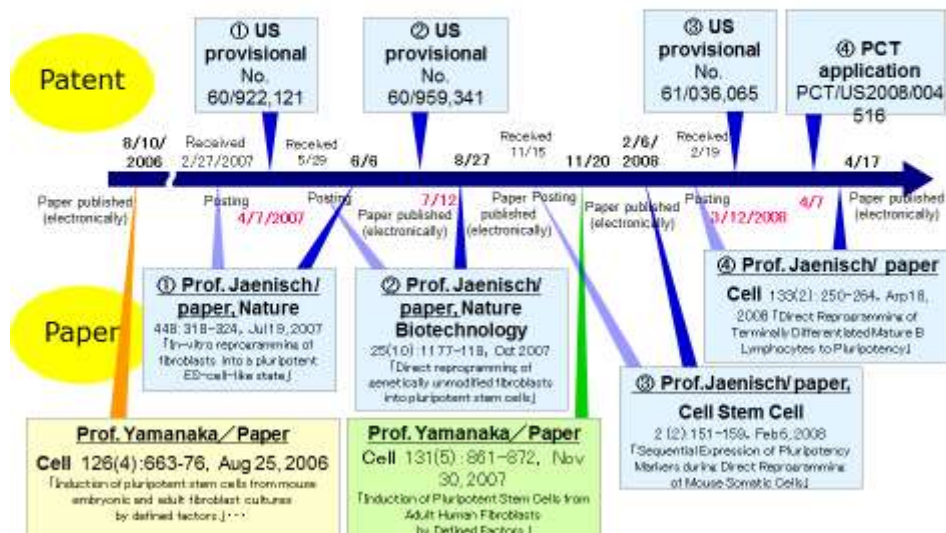
Professor Shinya Yamanaka obtained relevant patents by filing the patent applications before publishing an article, for which the professor later won the Nobel Prize. Professor Yamanaka filed patent applications with the JPO on December 13, 2005. He subsequently contributed an article to the leading life science journal *Cell*, in which the article was published on August 10, 2006. Obviously, the patent filing was made before the article publication. He then filed PCT applications one year after national filing and nationalized the applications in several countries including Japan one-and-a-half-years after that. This procedure is commonly performed in filing promising patent applications. On September 12, 2008, a patent was granted for one of the national phase applications in Japan as a basic iPS cell invention (Patent No. 4183742). The patented invention was a “method for producing induced pluripotent stem cells from somatic cells comprising a process of introducing the following four kinds of genes—Oct3/4, Klf4, c-Myc and Sox2—into the somatic cells” defined in the scope of the claims. This is the basic patent of the world-shaking, Nobel Prize-winning iPS cell technology.



Professor Yamanaka's article was contributed, and published, on dates after the filing date. As inventions are generally kept secret between article contribution and publication, there is no problem with patent filing during the period from article contribution to publication. The following presents a case of Professor Jaenisch, a prominent MIT Whitehead Institute researcher in regenerative medicine, like Professor Yamanaka. After the first-in-the-world publication of Professor Yamanaka's iPS cell article in *Cell* on August 10, 2006, Professor Jaenisch contributed an article on his research results to the journal *Nature* on February 27, 2007. He then filed a provisional application with the USPTO one-and-a-half months later, on April 7. This patent filing date came after the article contribution to the journal but before June 6, 2007, when the *Nature* issue concerned was published,

providing no disadvantages under the patent system. As described above, patent filing between article contribution and publication may be an acceptable compromise to ensure a win-win situation for researchers who want to contribute articles as early as possible, because such filing allows for article contribution early on and does not jeopardize patent application.

First to file; example2
iPS-cell patent application and paper
Prof. Jaenisch's case, Whitehead Institute, MIT

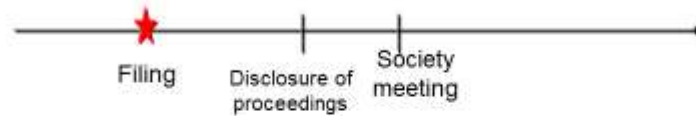


2. Grace Period and the American Invention Act (AIA)

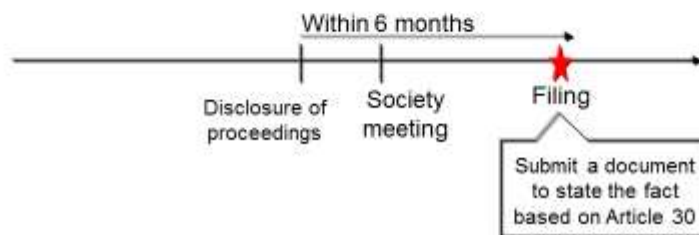
A grace period of a patent system gives consideration mainly to researchers at universities and public research institutions. Some countries, like Japan and the US, have a system in place that provides for a period—six months in Japan and one year in the US—within which a patent application filed for an invention after the publication of an article on the invention will not be rejected on the grounds of the published article. Grace period systems vary in details from country to country.

Recommended timing to file

1. Recommended timing



2. The next-best timing as an exception to the lack of invention novelty



42

The following compares the grace period systems of different countries. Comparisons are made regarding (i) the grace period, (ii) the necessity or unnecessity of an oath on filing, and (iii) the scope of disclosure without novelty being lost. (i) Countries such as the US have a 12-month grace period, while countries such as Japan have a six-month grace period. (ii) Patent applications are required to be filed under oath in all countries except the US. In swearing the oath, the applicant must identify any subject matters inadvertently disclosed before filing. (iii) The scope of disclosure without novelty being lost is unlimited in the US, but is limited in Europe only to exhibition at generally accepted international expositions. Accordingly, patent applications in Europe after presentation at academic conferences or in journals will end in failure, rejected because of such disclosure. In Japan, the scope of disclosure used to be limited to academic conferences approved by the Commissioner of the JPO, but the revised Patent Act effective in 2012 lifted this limit and expanded the scope to all conference presentations and publications made known to the public by the inventors and/or applicants.

It is quite interesting to note that the US-South Korea Free Trade Agreement (FTA) has resulted in the extension of the grace period in South Korea from six months to 12 months. This indicates that national patent systems may be changed even by bilateral economic agreement. As in the case of South Korea, Japan might extend its grace period from six months to 12 months when the Trans-Pacific Partnership (TPP) comes into effect.

Differences in Grace Period System between Countries (Region)

	US	Japan	Europe	China	South Korea
Purpose	To promote early filing	To relieve loss of novelty	To relieve loss of novelty	To relieve loss of novelty	To relieve loss of novelty
Grace period	1 year	6 months	6 months	6 months	12 months (Note 2)
Oath on filing	Not required	Required	Required	Required	Required
Applicable public disclosure	Not limited	·All disclosure where the invention has become publicly known by any act of the applicant. Amended patent law effective April 1, 2012 (Note 1)	·Display at an officially recognized international exhibition.	·First display at an international exhibition recognized by the government. ·First presentation at a designated academic conference.	·All disclosures where the invention has become publicly known by any act of the applicant.

Note 1: Before the new law took effect on April 1, 2012, the grace period did not apply to many types of disclosure. For example, it did not apply to presentations at undesignated academic conferences in Japan and those at most conferences abroad, including IEEE conferences. Disclosure on the Internet was applicable but TV coverage and broadcast was not. Catalogs (publications) were applicable but sales were not.

Note 2: The period has been extended to 12 months since the establishment of the US-South Korea FTA (effective on March 15, 2012).

These comparisons show that the grace period system in the US may be the most user-friendly. The US grace period system has become more beneficial since the American Invention Act (AIA) was signed into law by President Obama in 2012 (effective in 2013). The benefits of the system can be enjoyed by all applicants inside and outside the US who file patent applications with the USPTO.

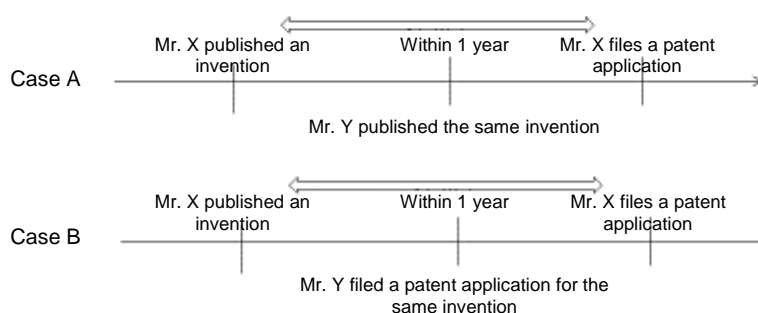
In the following cases, A and B, assume that Mr. X created and disclosed an invention, and after that Mr. Y happened to disclose the same invention (Case A) or apply for a patent for it (Case B). If, after that, Mr. X files a patent application within one year after the disclosure of his invention, according to the AIA, Mr. X will not be ruled out in either case—that is, by Mr. Y’s disclosure or patent filing—from obtaining patent rights to the invention. Naturally, in Case B, Mr. Y’s patent application will be rejected on the grounds of Mr. X’s disclosure.

As shown in these examples of operation, the AIA provides that the invention not be rejected, not only in the case of the applicant’s publication but also even if, within one year after that publication, a third party publishes or files a patent application for the same invention. Specifically, if, within one year after the date of publication of the invention, Mr. X files a patent application for the published invention with the USPTO, the time of application by Mr. X will be regarded as being applied retroactively to the time of publication by Mr. X for comparison with publications and applications by others.

US Patent Law Amendment (effective on March 16, 2013)

Point of amendment: Switching from a first-to-invent system to a first-to-publish system

- If an applicant has filed a patent application for an invention within one year after its disclosure or publication, the first date of disclosure or publication will be referred to determine who is entitled to the patent when two or more applications are filed for the same invention.
- The US grace period system is not an exception.



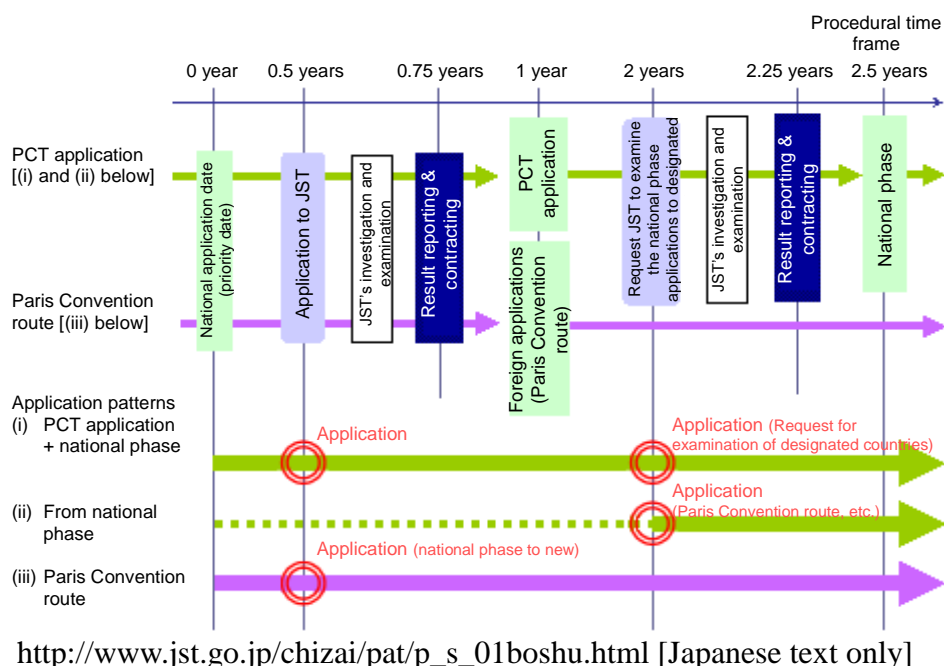
50

3. Use of National Support for Foreign Application

Foreign applications are highly costly, as described in 3.4 “Foreign Patent Filing.” In Japan, universities began to build an on-campus IP management structure around 2000 and have proceeded with its use. However, university research results take a dozen or so years of licensing to provide license fee income, partly because the results are generally basic (based on the experience of US universities).

Therefore, the IP management division has become a cost center for many universities, with its economic position becoming increasingly fragile. Meanwhile, foreign applications are highly costly. From a national policy point of view, the Japan Science and Technology Agency (JST) has established a system for loaning for filing foreign applications that fulfill certain conditions. The following outlines the JST's system. The system may be extremely helpful for universities that have an IP management base in the developing stages.

- (1) Main eligible applications:
International patent applications (PCT applications) filed by universities, TTOs and TLOs based on national applications
- (2) Receipt of application for support:
There are two stages of timings for application for support for filing foreign applications through the PCT route. In the first stage, the JST receives applications, at the time of six months elapsed after national filing, submitted by universities, etc., for loans for filing PCT applications. In the second stage, the JST receives applications, at the time of one year elapsed after the PCT applications, submitted for loans for national phase applications to designated countries and for costs to obtain patent rights in these overseas countries.
- (3) Determination to support:
In the first stage of application, the JST determines the innovation (novelty and inventive step) of the invention and its degree of impact in industrial applicability. In the second stage of application, the JST determines the patentability of the invention based on the international search report and the International Searching Authority's review, as well as the international preliminary report on patentability. It also requires the applicant to submit a licensing agreement or joint research agreement as indirect evidence for assurance of overseas technology transfer (requirement effective in 2015) to determine whether the technology will be transferred overseas. Based on these determinations, the JST will decide whether to support the applicant and how many overseas countries will be covered.
- (4) Support review:
The JST reviews support, once adopted, for necessity three years after the PCT application, and discontinues such support if it is deemed no longer necessary to continue with it. The JST can thereby allocate the remaining financial resources for support to other potentially patentable PCT applications.
- (5) Repayment of loan from license fee income:
If it obtains license fee income (initial royalty, running royalty, compensation for non-working of the patented invention, technology disclosure fees, optional fees), the loanee must repay such loan to the JST with 50% of the entire income per year until full repayment.



4. Examples of Acquisition of University-Originated Patents Using a Support System

Patents are meaningful only when used. In this sense, it is important to start technology transfer activities soon after patent filing and, at the transferee's request, proceed with patent acquisition. In other words, an invention, if unpatentable, will become useless to the licensee. Licensing agreements often require the licensed patent application to be registered in the patent registry. For this, the JPO's accelerated examination system is very useful. It also provides an opportunity for undergoing an interview with an examiner as needed. The following gives an example of university-originated patented inventions using these systems effectively.

The invention was invented by Professor Tadahiro Kuroda and three other members of Keio University School of Science and Technology, and a patent was applied for it by Keio University. In this case, the applicant was late in requesting examination (more than two-and-a-half years after filing) and had then to prove as early as possible that the invention should be patented-registered. Under the patent legal system of Japan, applicants may undergo accelerated examination if they satisfy any of the given conditions, including the fact that they are an SME or a university, and that their filed invention has been licensed. Applicants are not required to pay an extra charge for the examination. Although the JPO recently shortened the period from request to examination to about one year, it took about two-and-a-half years in 2008. Even at that time, the applicant requested accelerated examination, and, in turn, received an examination outcome (notification of reasons for rejection) within as little as one year.

If the notification of reasons for rejection suggests that the applicant and the examiner are arguing on different grounds, it is effective for the applicant to apply for and undergo an oral examination by the examiner to submit an appropriate amendment and written argument and amendment. Because the invention in question was novel but subject to misunderstanding, the oral examination was very effective

in giving the applicant an opportunity to explain the difference between the invention and the prior art references presented by the examiner. After that, the applicant submitted an amendment and written argument within the legal term, thereby obtaining a patent grant on May 21 of the same year. This was achieved in less than five months from the request for accelerated examination.

- (1) Patent application (Application No. 2004-037242) on February 13, 2004
- (2) Request for examination of application on December 12, 2006
- (3) Request for accelerated examination (with a statement of reasons submitted) on January 28, 2008
- (4) Notification of reasons for rejection on February 27, 2008
- (5) Oral examination on April 15, 2008
- (6) Submission of amendment and rebuttal argument on April 21, 2008
- (7) Decision to grant patent on May 21, 2008

5. Provision of Patent Information to Researchers

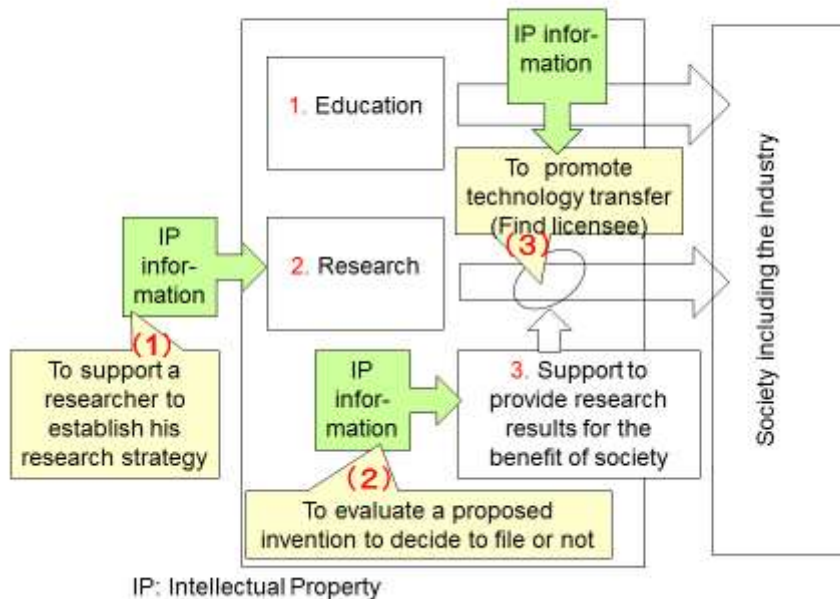
1. University Missions and Use of Patent Information

Universities in Japan have three missions, as mentioned in 1.4. In research, the second university mission, researchers are known for developing research strategies effectively by reference to patent literature in addition to articles. Depending on the advanced technology field concerned, as described later in 5.2, important research results may be disclosed only in patent literature. The patent document may be published before article publication.

In giving research results back to society, the third university mission, an invention submitted by a researcher is investigated to determine whether it satisfies certain requirements, and, depending on the result, becomes subject to patent filing management to determine whether or not a patent should be applied for. In the course of investigation, experts perform prior art search, as described in 3.3 “Patent Filing.” If almost the same invention is found to have been known to the public, a patent application will not be filed.

If the search finds no similar technology and the invention has novelty and an inventive step in comparison to prior art and is potentially highly marketable if put to practical application, the invention will become a candidate for patent filing. Once a patent application is filed for the invention, licensing activities will begin to existing companies aiming to put the invention to practical use. The above-mentioned patent literature search performed for determination of novelty and inventive step may be helpful in finding a licensee. Patent literature contains individual and corporate inventors who carried out the R&D for the patented inventions listed therein. Among such inventors, licensee candidates may be found.

Three missions and utilization of IP in a university



11

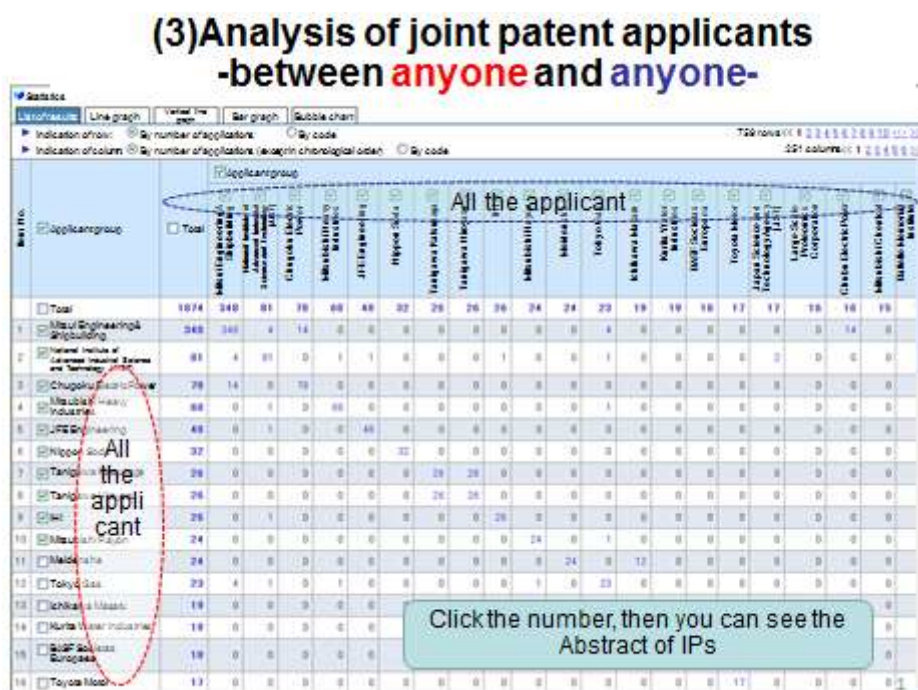
2. Use of a Patent Map

The JPO receives about 300,000 patent applications every year. Most of these applications are disclosed one-and-a-half years after filing in the Kokai publication of unexamined applications. The Kokai publication contains technical descriptions (specifications) and claimed rights (the scope of claims) of the inventions, as well as the inventors and patent applicants (many of which are companies). Therefore, processing and analysis of Kokai publications collected for a certain period can help in learning development trends in particular businesses and technology trends, in particular, in technical fields. Graphs and diagrams of such trends visualized through processing and analysis are called patent maps. These patent maps, a tool that is effective in developing R&D strategy, should be provided to researchers at universities and research institutions.

5.2.1 and 5.2.2 below give examples of patent maps created by Hitachi Information Service under entrustment to track trends in methane hydrate R&D. Through these examples, seek effective ways to use patent maps.

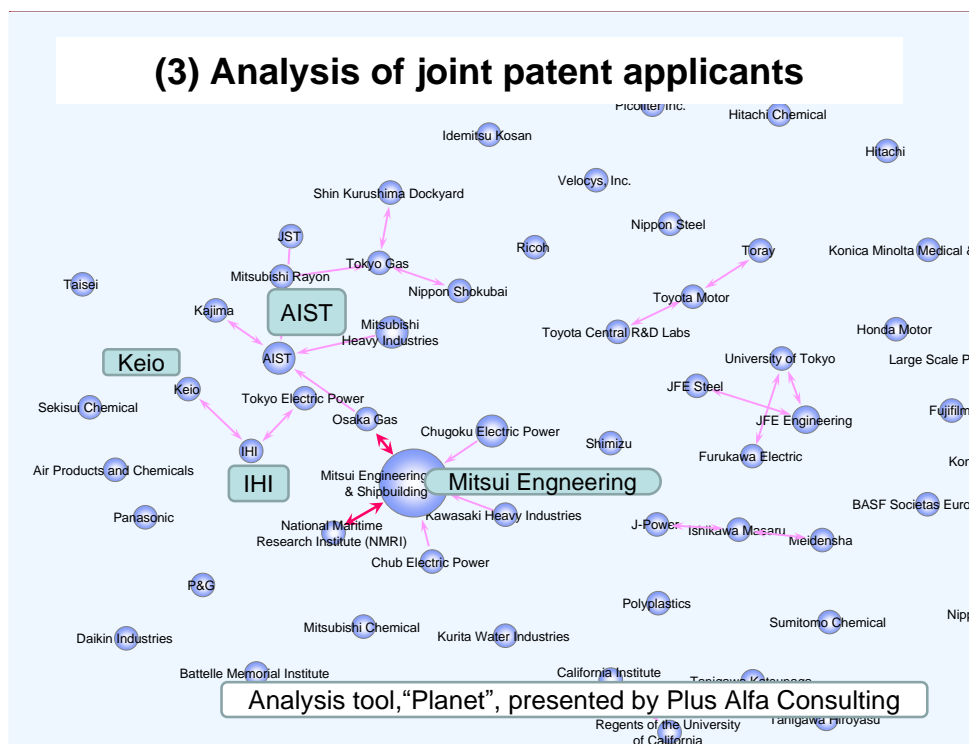
5.2.1 Use of Joint Patent Information

The Kokai publication sometimes lists the names of co-applicants. This indicates that joint research and/or joint development was carried out between the co-applicant companies. As a result of the joint research, the co-invention was created. Therefore, the companies to which the inventors involved in creating the invention belonged filed the application under joint signatures. The combinations of companies in joint research and/or joint development can be tabulated as shown below. With the applicants arranged on the vertical and horizontal axes in descending order of the number of applications, the table shows the numbers of joint applications filed by the applicants on the vertical and horizontal axes at the points of intersection of the rows and columns. It gives at-a-glance patterns of combinations in joint research, indicating which companies and universities filed how many joint applications of joint research results. The numbers at some points of intersection can be clicked to display relevant Kokai publications.



The following diagram provides a more user-friendly map of analysis visualized using +Planet, a tool developed by Plus Alpha Consulting. The bubble size indicates how many applicants the corporate applicant has filed. Arrows between bubbles indicate joint research and/or joint development that have taken place in cooperation between the applicants, that is, between companies, and between companies and universities. The arrow size indicates how many joint applications have been filed.

In this technical field, for example, the diagram shows that Mitsui Engineering & Shipbuilding has filed by far the largest number of patent applications. Mitsui Engineering & Shipbuilding has also carried out joint development with several companies. The map also shows Keio University has conducted joint research with AIST and IHI.



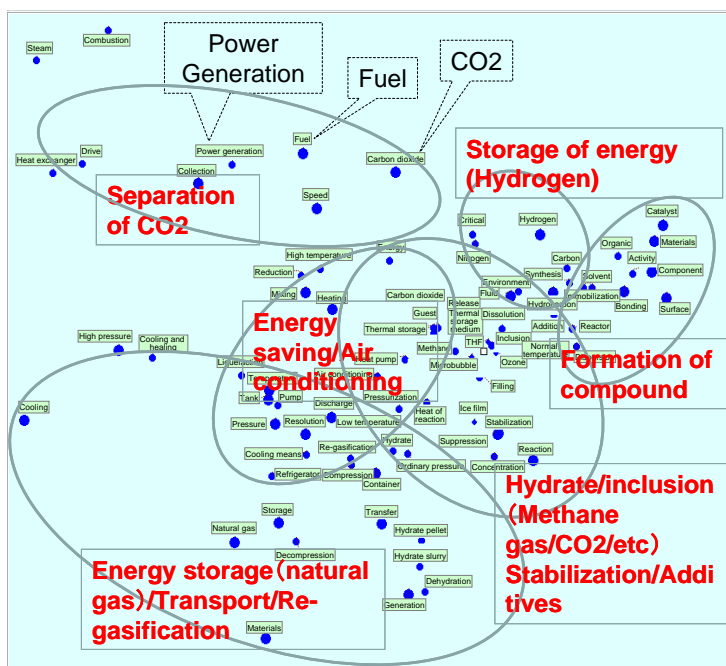
5.2.2 Tracking trends in R&D in specific technical fields or by specific applicants

The following diagram is created by True Teller Patent Portfolio, a tool developed by NRI Cyber Patent. This tool can analyze text mining on filing specifications in specific fields or by specific applicants (companies, universities, etc.), thereby providing an at-a-glance picture of what technical theme R&D is focusing on.

In step 1, count the frequency of combinations of two technical terms—for example, “compression” and “heat of reaction”—in all the patent specifications in the technical field that you want to analyze. The two technical terms are placed according to the rule that they are closer to each other when the count is larger and farther from each other when the count is smaller. The vertical and horizontal axes have no meaning.

In step 2, create several groups based on the distribution of the technical terms, then name the groups. In this case, for example, the groups are assigned with superordinate concept names such as “hydrate/inclusion,” “energy saving/air-conditioning technology,” “energy storage (natural gas),” “formation of compounds,” and “energy storage (hydrogen).”

(4) Analysis of Research Theme

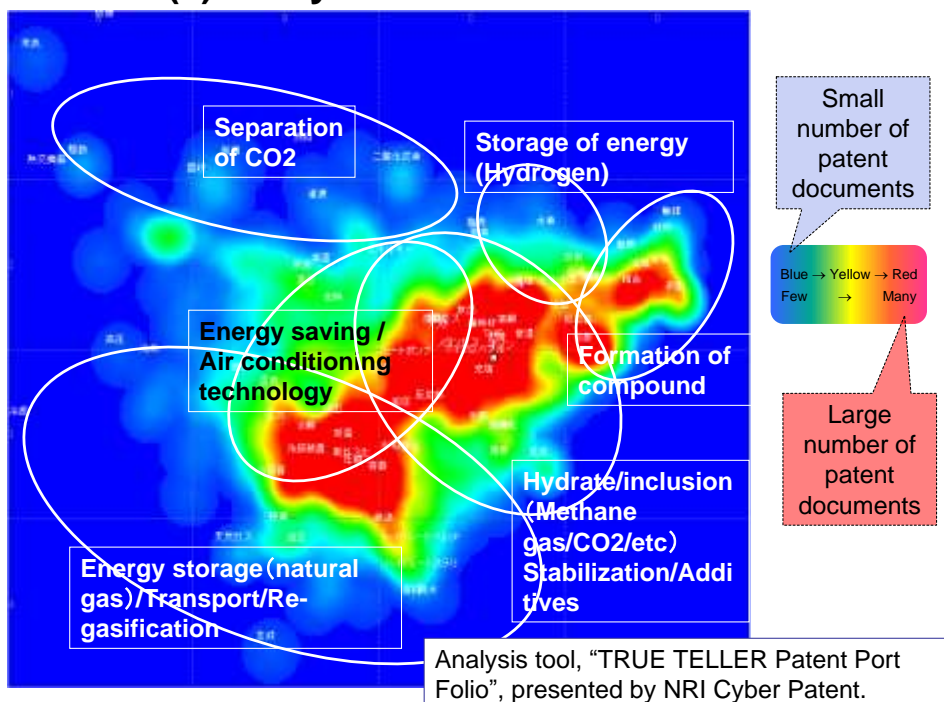


- We count the number of appearance of the combination of two words in one document.
- The bigger the number of appearance in a document, the smaller the distance of two words

Analysis tool,
“True Teller
Patent Port
Folio”,
presented by
NRI Cyber
Patent.

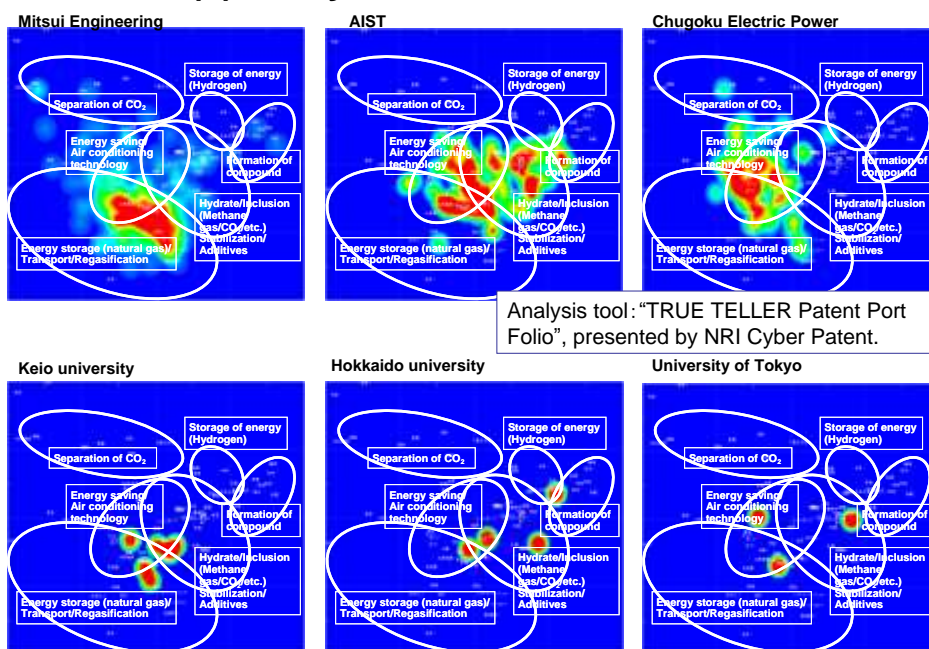
You then obtain a map of technical terms in the specific technical field. In this map, color the combinations of the terms with the largest number of patent documents containing the combinations in red, and those with the smallest number of such documents in blue. Between them, the color should be changed in rainbow-like gradation from red to yellow and green to blue. As a result, the red area means that there is a large number of relevant patent documents therein, suggesting that R&D is focusing on this area. This is known as a heat map.

(4) Analysis of Research Theme



The following are heat maps created by an applicant. The top three companies are on the upper-row, while the top three universities are on the lower row. Red areas in the maps vary in position, size and form from applicant to applicant, showing the difference in focus areas between the applicants at a glance. The focused research areas also vary widely from university to university. Analysis of these distribution patterns indicates the strengths and weaknesses of each company or university. The maps may provide those who intend to advance R&D in this technical field with an important clue in selecting a collaboration partner: which companies the universities should work with, and vice versa.

(4) Analysis of Research Theme



3. Indispensable to Provide Patent Documents to Researchers in Regenerative Medicine

This chapter explains that even in regenerative medicine, a field in which considerable importance is placed on scholarly activities, research results are often known only from Kokai patent application publications, not from articles. The chapter also provides examples where even if both the article and the Kokai patent application publication are available, the Kokai publication was released considerably earlier than the article. Given the current situation in this field around the world, it may be vital in research strategy development to frequently provide researchers with patent documents.

Remarkably rapid advances have been made in R&D in regenerative medicine since Professor Shinya Yamanaka of Kyoto University, Japan published an invention of the century known as iPS cell technology, for which he received the Nobel Prize in Physiology or Medicine for 2012. Professor Yamanaka first published his iPS cell research results in December 2005. Less than 10 years later, he received the Nobel

Prize. This is a rare case, which illustrates how his achievement has had a great impact on society. Regarding the chronological relationship between article publication and patent filing, as described in 4.1 “Paper and Patent,” Professor Yamanaka both published articles and filed patent applications for his invented iPS cell technology in an appropriately timely manner. In short, the patent application was submitted earlier than the article.

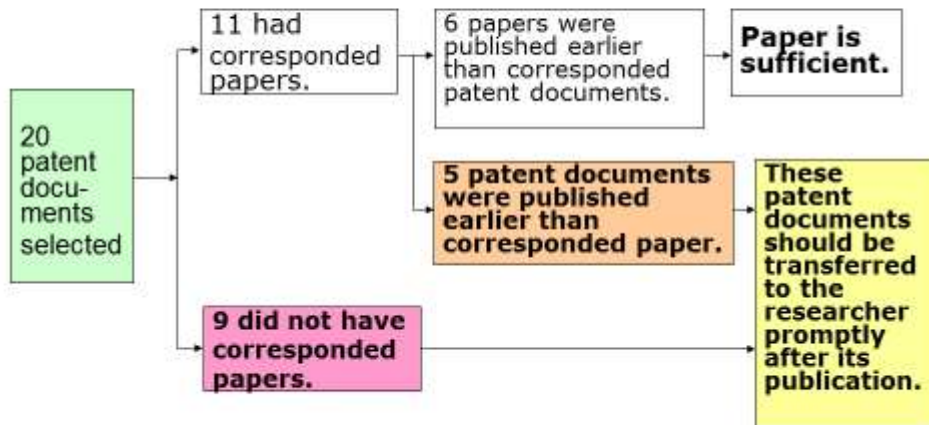
Therefore, this section provides an investigation of whether important research results in this hot field of research are submitted and disclosed both as patent applications and articles. The author searched patent documents published for about one-and-a-half years between March 1, 2010 and September 30, 2011, only in nerve regeneration because there were too many patent applications filed in the entire field of regenerative medicine. Although the scope of search was limited, the parameters encompassed more than 600 USPO applications, 500 PCT applications (published by WIPO), and 200 JPO applications, indicating that the field was extremely research-intensive. Among the applications, the author selected 20 noteworthy applications and searched for articles relevant to them. Relevant articles were found for 11 applications but not for the remaining nine applications (i.e., nine patent-alone disclosure cases). Of the 11 patent application publications with articles corresponding to patent applications, six applications were disclosed to the public after article publication, and five applications were disclosed earlier (i.e., five prior patent disclosure cases).

There may be possible reasons for this. First, in the patent application system, patent applications are automatically disclosed one-and-a-half years after filing unless they are withdrawn. Second, in the globally accepted first-to-file system, the right to the granting of a patent for the same invention lies with the first person to file a patent application for that invention. Therefore, pressure mounts for patent applications to be filed as early as possible when the given requirements are satisfied. Meanwhile, article publication may be delayed even though the article is contributed around the time of the patent filing because data additions or revisions may be repeatedly made to the article in the review process of the journal, especially if it is prominent.

Researchers could not first find the inventions of these nine patent-alone and five prior patent disclosure cases in articles. The published patent documents on them must be provided to researchers because such documents serve as a source of information on research results to be disclosed at the earliest timing in the world.

Result in the field of regenerative medicine
JP,US,WO (PCT)

published period: March 1, 2010-September 30, 2011



The following details the nine patent-alone disclosure cases without the publication of relevant articles. The applicants include companies, but remarkably many of them are academic institutions, such as California Institute of Technology, the University of Michigan, and Gladstone Institutes.

The author conducted a follow-up search on the nine cases for an extension to March 2012, discovering an article that corresponded to the sixth patent-applied invention in the table below. The author found that the article was published in *Cell Stem Cell* in January 2012, and the patent was disclosed in June 2012. In addition, as indicated by the article's title—"Direct reprogramming..."—it was found to describe a crucial research achievement of direct differentiation into target cells (neural stem cells) without going through iPS cell generation.

Cell Stem Cell 2012 vol.11 pp.100–109, "Direct reprogramming of mouse and human fibroblasts into multipotent neural stem cells with a single factor"

9 patent documents did not have corresponded papers.

	Application No.	Published	applicant	title
1	11/397200	2007-25975	California Institute of Technology(US/CA)	Oligodendrocyte determination genes and uses thereof
2	12/935427	2011-91927	HADASIT MEDICAL RESEARCH SERVICES & DEVELOPMENT	MOTOR NEURONS DEVELOPED FROM STEM CELLS (Example 1)
3	12/813174	2011-2897	Burnham Institute for Medical Research(US/CA)	DIRECTED DIFFERENTIATION OF STEM CELLS
4	12/872397	2011-189184	NeuroNova AB(SE/)	MODULATION OF NEURAL STEM CELLS AND NEURAL PROGENITOR CELLS
5	PCT/US2011/023259	WO/2011/097181	VIVOSCRIPT,INC.	COMPOSITIONS AND METHODS FOR RE- (Example 2) PROGRAMMING CELLS WITHOUT GENETIC MODIFICATION FOR TREATMENT OF NEUROLOGICAL DISORDERS
6	PCT/US2010/055836	WO/2011/059920	THE J. DAVID GLADSTONE INSTITUTES	METHODS OF GENERATING NEURAL STEM CELLS
7	PCT/CA2010/001727	WO/2011/050476	NEW WORLD LABORATORIES INC	METHODS FOR REPROGRAMMING CELLS AND USES THEREOF
8	PCT/US2010/037789	WO/2010/147803	REGENTS OF THE UNIVERSITY OF MICHIGAN	Adult cerebellum-derived neural stem cells and compositions and methods for producing oligodendrocytes
9	12/698757	2010-135968	Stem Cell Therapeutics Inc.(CA/)	Oligodendrocyte Production From Multipotent Neural Stem Cells

Of the 11 applications with published relevant articles, three of the five prior patent disclosure cases are highlighted in color below, of which three were with patent documents disclosed around one year earlier than the relevant articles. Considering that there are cases where patent applications were disclosed considerably earlier even with articles published that were relevant to the patent documents, as mentioned above, it would be necessary to provide researchers with published patent documents in their fields soon after disclosure.

11 patent documents had corresponded papers.					
Filing No.	Patent No.	Patent Title	Patent Description	Patent Field	Disclosure timing
1	PCT/US2009/065007	WO/2010/059738	DEPARTMENT OF HEALTH AND HUMAN SERVICES (US/US);	DIFFERENTIATION OF STEM CELLS INTO DOPAMINERGIC CELLS	Stem Cells
2	Patent Application No. 2010-017013	Patent Publication No. 2010-162024	Wisconsin Alumni Research Foundation	Method of in vitro differentiation of neural stem cells, motor neurons, and dopamine neurons from primate embryonic stem cells.	Nat Biotechnol Stem Cells
3	12/710097	2010-239541	Neuralstem	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEURODEGENERATIVE CONDITIONS	Transplantation PLoS Med
4	13/054692	2011-217774	Industry-Academic Cooperation Foundation Yonsei University(KR/)	Efficient and Universal Method for Neural Differentiation of Pluripotent Stem Cells	Stem Cells
5	12/995988	2011-135696	The McLean Hospital Corporation(/)	MULTIPOTENT NEURAL CELLS	Stem Cells
6	12/824872	2010-323444	UNIVERSITY OF FLORIDA RESEARCH FOUNDATION(US/FL)	CULTURING AND DIFFERENTIATING NEURAL PRECURSOR CELLS	Development
7	12/365381	2009-196859	Georgia Health Sciences University(US/GA)	Oligodendrocyte precursor cell composition and methods of use	Neurochem
9	12/806907	2011-81719	Wisconsin Alumni Research Foundation(US/WI)	Substantially pure human retinal progenitor, forebrain progenitor, and retinal pigment epithelium cell cultures and methods of making the same	Proc Natl Acad Sci USA
9	PCT/US2011/021731	WO/2011/091048	THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY	DIRECT CONVERSION OF CELLS TO CELLS OF OTHER LINEAGES	Nature Cell Stem Cell
10	PCT/US2010/039686	WO/2011/005581	LPATH, INC.	METHODS OF INCREASING NEURONAL DIFFERENTIATION USING ANTIBODIES TO LYOPHOSPHATIDIC ACID	Stem Cells
11	12/404841	2010-55075	NeuralStem	METHODS OF TREATING ISCHEMIC SPASTICITY	Neuroscience

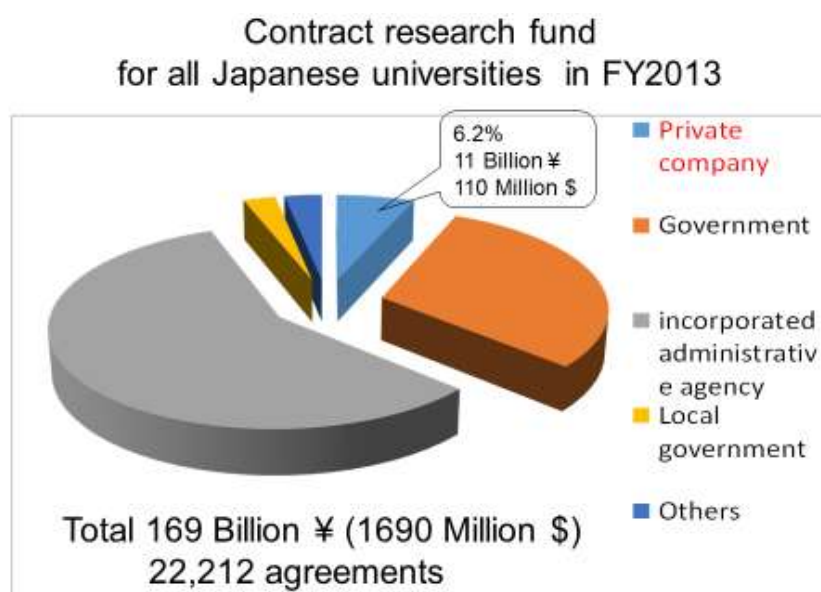
6. IP Management in Joint Research and Contract Research

1. Acquisition of Research Funds at Universities

Universities' intellectual property comes from the pursuit of the second university mission—research. As a result of the promotion of research, new knowledge is created, leading to inventions or other intellectual property. To promote research, universities need to secure research funds from outside sources. Universities obtain income mainly from students' fees. Researchers, therefore, have to raise research funds from outside the universities. This trend is especially apparent in Japan, where private universities make up about 80% of all universities.

Research funds raised from outside sources consist mainly of contract research funds and joint research funds. Moreover, some universities may switch license income to research funds if they are successful in technology licensing.

According to MEXT statistics, the total of outsourced contract research funds received by universities in Japan is 169 billion yen per year (see the figure below, statistics for FY2013). The breakdown of the funds shows that competitive funds from the government and government-affiliated organizations (for example, JST, JSPS and NEDO) comprise a majority of contract research funds. Only 6% comes through university-industry collaboration from the private sector. This indicates that a small proportion of the contract research funds are used for research that companies directly need, while most are used for basic research deemed by the government to be necessary from a long-term perspective.



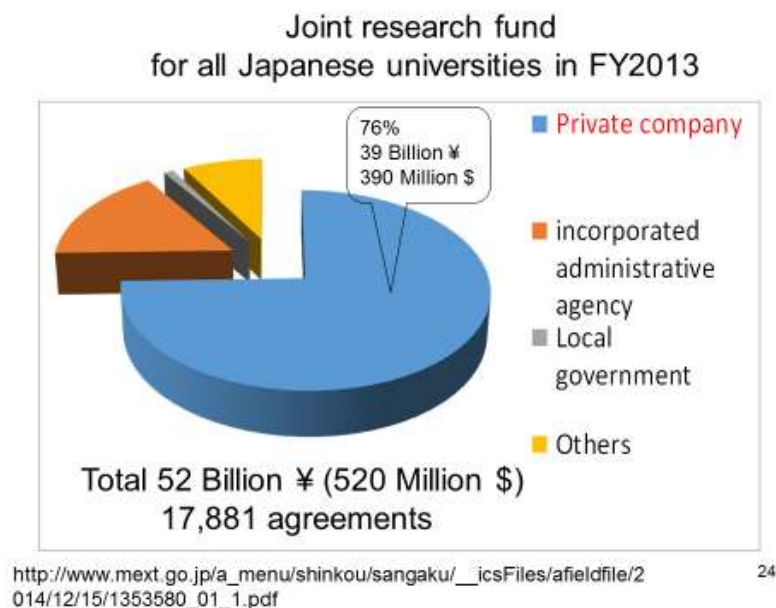
http://www.mext.go.jp/a_menu/shinkou/sangaku/_icsFiles/afieldfile/2014/12/15/1353580_01_1.pdf

25

According to the same MEXT statistics, joint research funds received by universities in Japan from outside organizations total 52 billion yen per year. This represents almost one-third in amount of all contract research funds. Seventy-six percent of joint research funds come from the private sector. This indicates that joint research funds are mainly used for research that may be linked to industrial

applications, rather than companies' direct needs, while most are for basic research deemed by the government to be necessary from a long-term perspective.

Researchers in such contract research and joint research projects are expected to reveal new findings through projects that would be translated into articles with high impact factors. Researchers should also contribute their research results to the creation of intellectual property rights in, for example, patented inventions to give back to society as the third university mission. An apparent trend to do so is found particularly among researchers in corporate-sponsored research projects. However, this trend is also increasingly emerging among those in projects with competitive research funds granted by the government.



2. Why Do Universities Conduct Joint Research (Tie Ups with Companies)?

Joint research means research that two organizations jointly conduct research on a common theme by sharing their respective resources. It aims to achieve new research results that would not otherwise be attainable, to create new intellectual property as well as to accumulate know-how. It has the following advantages in general: (i) the two organizations can complement each other; (ii) they can reduce development risk; and (iii) they can shorten the period of development. (i) Joint research provides complementarity in terms of resources between a company with R&D funding resources and a university short of funds but with a research structure including researchers and research environments. Another complementary aspect may be found in terms of their respective research strengths. This is because, in general, universities are strong in basic research while companies are strong in applied research and product development. Such university-company tie-ups pave the way for universities to give their research findings back to society via industry. (ii) Joint research reduces development risk. Even if difficulties occur in the course of the research, they are easier to overcome, by being diversified between the two organizations. (iii) Joint research shortens the period of development in comparison to independent research, by expanding and building up, through collaboration, the development structure and

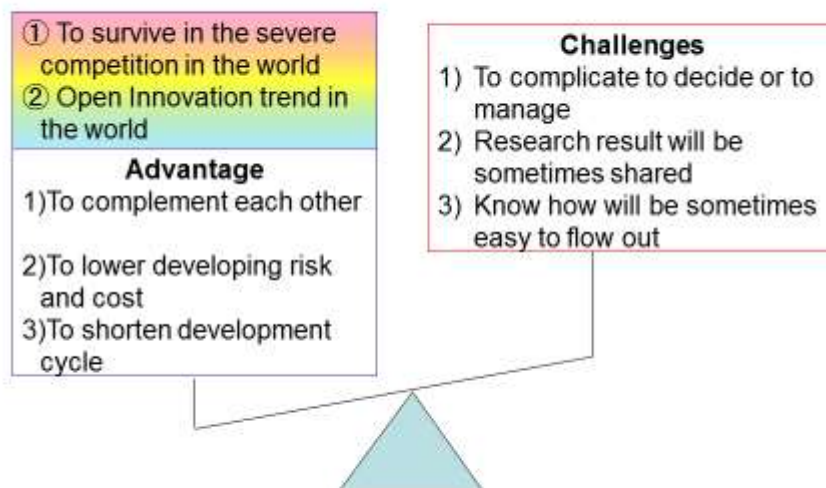
development funds.

Meanwhile, joint research may also present challenges. Challenges may include (i) research management becoming more complex, (ii) research results becoming jointly owned, and (iii) joint research organizations having their secrets leaked to each other. (i) Research management will become complex in joint research if the need arises in the course of the research to decide, for example, whether to change the scale of the research. This is because the joint research organizations have to agree on such matters, unlike in the case of independent research where such decisions may be easy to make. (ii) Regarding joint ownership of research results, the Patent Act provides that, for example, if multiple parties have jointly created an invention, the right to obtain a patent therein should be jointly owned. If a right is jointly owned as above, limitations that would not arise in independent research will apply to the use and disposition of the right.

Although these advantages and challenges are mutually contradictory, expectations for joint research are rising amid recent global mega-competition and the progress of open innovation, as detailed in 9.1 “Toward a World of Open Innovation.”

Relying on open innovation, it is expected that companies can develop and roll out world-leading business strategies, for example, through joint R&D with universities around the world that produce research results most suitable to their future vision, and at the same time through manufacturing based on such results in collaboration with outstanding companies in terms of quality, price, and speed.

Severe competition accelerates Joint R&D.



57

3. Flow of Joint Research, and Necessity of NDA

The following provides a general flow of joint research. As the start of joint research, suppose, for example, that a university researcher presents research results at an academic conference, attracting the interest of participants from a company that is in charge of development, and subsequently the university and the company launch a

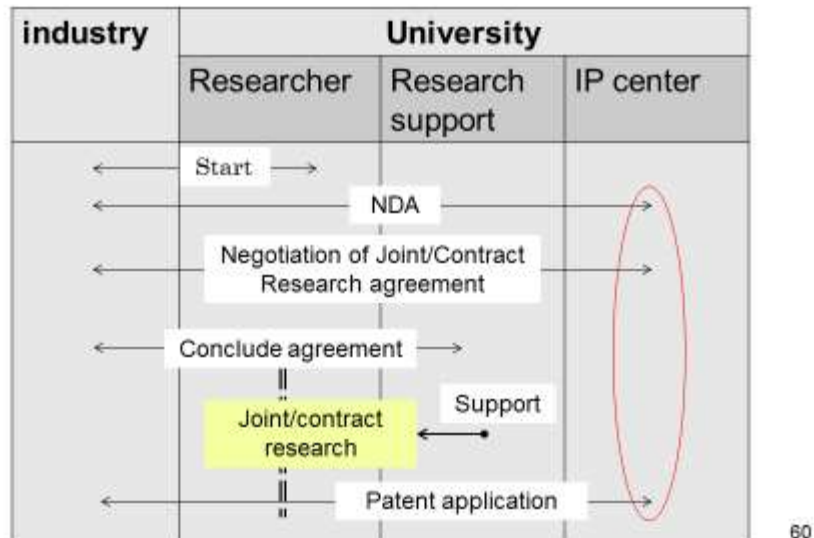
study to determine the feasibility of joint research. As the discussion enters full swing, it usually gets to the heart of the matter regarding information and know-how that should be kept confidential. At that time, both parties, in most cases, sign an NDA, or non-disclosure agreement.

If, without signing an NDA at this stage, the parties later fail to reach an agreement on joint research, the two parties can no longer protect their confidential information disclosed so far to the other party. If both sides reach a joint research agreement, a confidentiality clause may be introduced into that agreement that requires each of the parties to keep retrospectively confidential information disclosed by the other party; however, it would be safer to conclude an NDA. It is obviously unnecessary and maybe efficient to conclude an NDA if both sides discuss, only based on published information, to agree on joint research. However, an NDA may be considered as an indicator of how eager the counterparty is to proceed with the conclusion of a joint research agreement.

Joint research should not start without the conclusion of a joint research agreement. One reason is that it is too late to discuss the conditions for handling research results after they have been produced. Joint research agreement should include (i) the purpose, (ii) the roles of the participants, (iii) the sharing of research expenses, (iv) the setting of the research environment including staffing and site selection, (v) the handling of research results, and (vi) the jurisdiction. Of these, (v) the handling of research results will be the most important issue in the negotiation. Experts at the on-campus IP center, who are most familiar with this issue, will therefore usually take charge of negotiations. Details regarding this will be described in 6.4 and 6.5. Only after these matters are agreed through negotiations will joint research start.

After the start of joint research, the research support department will assist in purchasing goods and managing payments for them. If an invention comes from the research, the on-campus IP management office will consult with the counter-party company's IP department to decide whether to apply for a patent for the invention and to fix the terms and conditions of cost sharing, etc.

How to manage Joint/Contract research agreement ?



60

4. Negotiations for a Joint Research Agreement

The matters that a joint research agreement should cover have been described in 6.3 above. In the case of university-company joint research, the agreement may require that the university and the company expend efforts to agree on (i) the handling of intellectual property resulting from the joint research, (ii) the timing of article publication and conference presentation, and (iii) the setting of a research theme. It is ideal to negotiate an agreement that is a win-win for both parties. As joint research is intended to produce results jointly, an agreement that would leave either party as the only winner would not motivate the loser to proceed with joint research for success.

However, joint research between two parties with completely different backgrounds and missions, such as a university and a company, may often face difficulties if the two parties are new to each other because they have to research jointly in accordance with common guidelines or a common code of conduct. For example, companies wish to keep joint research results confidential for as long as possible, to file patent applications for the results rather than article publication. Meanwhile, university researchers are often keen to disclose research results. They want to write and publish articles on the results as early as possible. To bridge such differences in ways of thinking, both parties have to agree to compromise.

The first issue concerns the handling of intellectual property resulting from the joint research, as described in 6.5.

The second concerns the timing of article publication and conference presentation, the details of which are described as follows. If the joint research produces research results, the company will request that the new research results be kept confidential for a given period. It will also often request a two-month period for

considering whether the research results are worth filing a patent application for before the university researchers prepare and present the results at an academic conference or as a journal publication. Meanwhile, the university would take the view that this two-month period should be set before the results are disclosed in an abstracting journal or published as an article, not before article contribution.

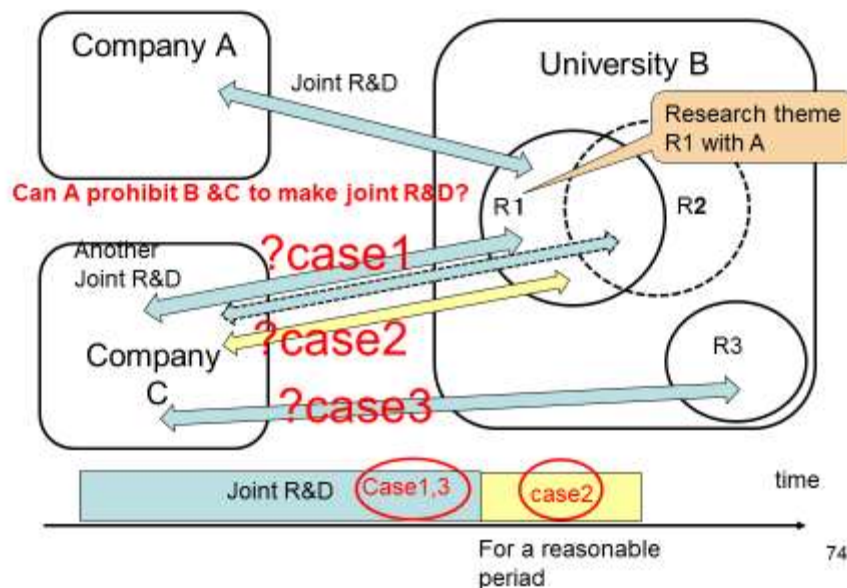
	University	Company
Culture	<ul style="list-style-type: none"> • Disclosure-minded • Values distribution of research results • University's responsibility for information dissemination 	<ul style="list-style-type: none"> • Confidentiality-minded • Research results include much company-confidential information • Intellectual property information is a lifeline for corporate management.
Example agreement clause	The University must provide the Company with a draft of an article the University plans to publish, at least two months before the article publication.	

The third issue concerns the setting of the joint research theme.

The university would expect opportunities to conduct joint research with multiple partners, if possible, to gain reach funds. As shown in the example below, assume that University B is conducting joint research with Company A under Theme R1. At this time, could University B conduct joint research with another company, Company C, under the same Theme R1? Alternatively, could University B conduct joint research with Company C under Theme R2, which is slightly different from Theme R1? The answer to both is generally no. This is because new research results from joint research between Company A and University B may be leaked via University B to Company C, which would have an adverse impact on Company A. In addition, the limitations imposed on University B may continue in effect, for example, for about one-and-a-half years even after completion of the joint research (see Case 2 below). Note that University B may at any time conduct joint research with Company C under Theme R3 independent of Themes R1 and R2.

In this way, University B's research Theme R1 seems to be monopolized by Company A. Considering such possible leakage of research results, however, there is no problem under Japan's anti-monopoly law because there is no inhibition of fair competition. Of course, if Companies A and C agree, University B may conduct joint research with Company C under both Themes R1 and R2.

Negotiation as to the target research theme in the Joint R&D with third party C



5. Handling of Intellectual Property under a Joint Research Agreement

This section describes an agreement on patent filing for an invention created from joint research (“joint invention”). Since around 2000, universities in Japan have had an intellectual property management system in place whereby they retain the ownership of rights to inventions originated from them, and file patent applications and maintain patents by themselves. Patent applications are for inventions of two types: university-alone inventions and joint inventions. In the handling of joint inventions, universities and their corporate partners have faced difficulties and accumulated much experience. The reasons for such difficulties may include the following: (i) this was the first experience for the university to conduct a joint invention and joint application with a company; (ii) the university struggled to have its corporate partner understand its patent policy, which differed greatly from the partners’ policy because the university did not work its inventions on its own, unlike the company; and (iii) the company, accustomed to conducting joint inventions with other companies, was for the first time handling a joint application with a university, which did not work its invention.

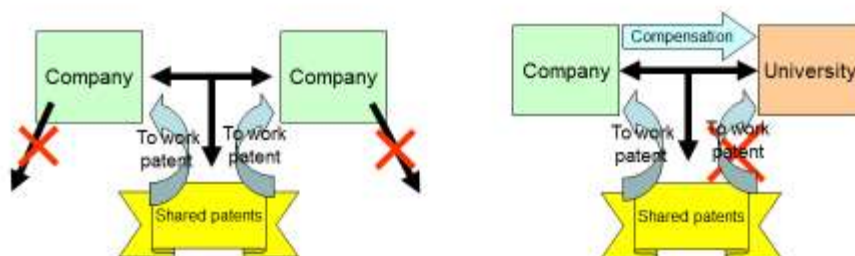
Jointly owned patent rights are specified in Article 73 of Japan’s Patent Act (for reference, see 10.4 “Related provisions of patent laws”). According to this article, as shown in the lower left, each of the joint owners of the patent right may work the patented invention (for its business) without the consent of the other joint owners (Article 73.2) but must obtain the consent of all the other joint owners if it wishes to grant a license with regard to the patent right to any third parties (Article 73.3). When these provisions apply to patent rights jointly owned by companies, they may essentially face no problems as all the owner companies are capable of working the patented invention. However, these provisions may be disadvantageous to universities in collaboration with businesses, as in the case of university-company

joint research. In other words, as shown in the lower right, no advantage will be brought about to universities even if they are at liberty to work their patented inventions from joint research because they cannot do so by themselves. Of course, universities may exceptionally work inventions in the course of research, but this is far from commercialization.

Under this article, the partner company can work the patented invention as if it is patented solely rather than jointly. The company can, therefore, enjoy extremely significant advantages in comparison to the university, which has no capability to take advantage of the invention. Universities therefore take measures, which can be broadly divided into the two categories below:

- (1) Establishing a condition in the agreement that if the partner company works the patented invention, the company should give part of the profits therefrom back to the university. This is known as “compensation for non-working of the patented invention.” This is known as “non-working compensation,” with the objective of compensating the university for the fact that it does not work the patented invention (non-working).
- (2) Having the partner company bear the patent application expenses in full. Depending on the industry, the partner company may sometimes accept this condition and sometimes not. If the company does not accept the condition, the university will propose as a first compromise that the company offset the university’s portion of the already paid application expenses in stages from the non-working compensation that the enterprise would otherwise pay to the university if the company worked the patented invention in the future. Other than this compromise proposal, the university would assign its respective share to the company for profit. In this case, it is necessary to remember to ensure that the university can use the patented invention at will for research purposes on campus.

Handling of shared ownership patents under the Japan Patent Act



< Issues specific to universities >

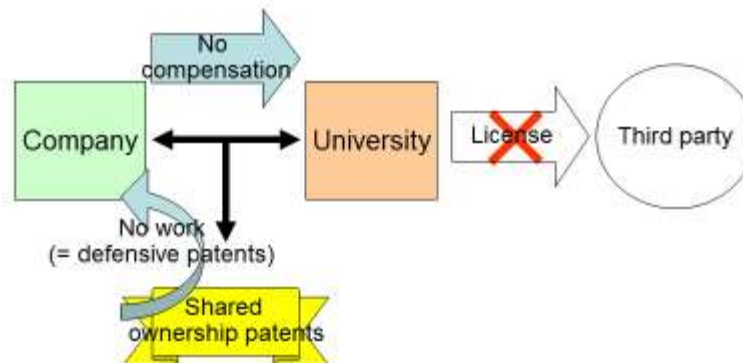
- Universities do not work patent rights. Therefore, they want compensation from other parties that do so.

The following paragraphs describe a case where the university suffers the most in handling a joint invention as mentioned above.

The case may occur when the joint invention becomes a “defensive patent.” A defensive patent is a patent that a company uses with the intention of defending its business from third-party attacks, as illustrated in the figure below. For example, assume that an enterprise, which operates business using a patented invention, obtains patents for several improvement inventions based thereon. If the company introduces the patents for the improvements into its business, its business operations will become more efficient. However, if the introduction is highly costly, the company will not do so (will not use the patents on its own), while at the same time the company will not allow competitors to use the patents. As a result, the patents will become patents that nobody uses. Such patents are called “defensive patents.” According to JPO statistics, defensive patents account for about one-third of the patents registered with the JPO. This ratio indicates that joint inventions created through university-company joint research are significantly likely to fall under this type of patent protection. If the joint invention comes with defensive patent protection, the invention will not be worked. Therefore, the university will not be able to receive compensation for non-working of the patented invention. At the same time, given the nature of a defensive patent, the partner company will not allow the university to license it out to a third party even if it wishes to do so. In addition, if the university has to share the patent application costs, that would be the worst case scenario for the university.

To prevent these problems, the university may need to have the joint research agreement include the provision that if the partner has neither plans nor prospects to work the invention even after the elapse of a specified time limit following the patent filing, the university may license the joint invention out to a third party without the joint partner’s consent, or may assign it to the partner company on the condition that the company pay considerable consideration to the university.

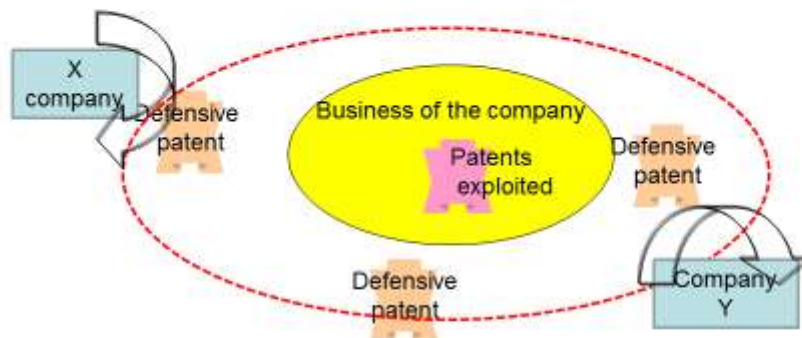
Conditions that would make shared ownership a tragedy for universities under Japan Patent Act



48

What is a defensive patent?

- This is a patent strategy used often by companies.
- The patent holder does not exploit it or allow others to use it. As a result, the patent holder protects his/her business from attacks by others.



65

7. University-Launched Startups

1. Why Are Startups Necessary?

Assume that a university has produced innovative research results and has filed a patent application for a technology based on such results with high expectations. To

give the results back to society, the university offers licensing or joint research to an existing company. The company considers but, as in most cases, declines this offer. This largely reflects the company thinking that university-generated technologies are high risk. The company's negotiators do not want to take this risk. They are afraid that they might be held responsible, in the case of failure, for funding the development of the university's new research results. Rather than shouldering a new project with a low probability of success, they can defend themselves by managing existing projects, even if less profitable.

However, such a way of thinking is unfavorable from the perspective of national policy, even though it may be acceptable at the individual company level. This is because any industry that operates simply by continuing, as before, to follow existing business models without embracing new ones, will eventually go into decline under global mega-competition. The government is, therefore, promoting business startups as its policy, while METI and MEXT are playing pivotal roles in the policy process in terms of developing new industries and encouraging research-based universities to create new technologies that deliver innovations, respectively.

Regarding the conservatism of existing companies as mentioned above, similar cases are reported not only in Japan but also in the US. Examples include the case of Google's search engine—introduced as Case 2 in 1.4 “Conversion of Research Results into Benefits for Society”—in which no existing companies were reportedly interested. In such a case, researchers, if enthusiastic about their research results like the Google founders, can set up a startup by themselves to put the results to practical application with the aim of giving back to society. Particularly in the US, there is the idea of the “American dream,” a culture of seeking high risk and high return. Failures are viewed positively. Financial backers called “angels” do not loan to, but rather invest funds in, startups of the high-risk high return type. Since investment does not entail lending funds, invested startups are not left with debt even if they fail.

Important matters in setting up a startup are: first, developing a business plan; second, recruiting a top manager; and third, seeking financial backers to fund the development activities.

As inventors, researchers should remain in charge of technical affairs at their newly founded startup because a conflict of interest is likely to occur if they serve both as a university researcher or teacher and as the startup president (see 8. “What is a Conflict of Interest?” for details).

One goal of a newly founded startup as mentioned above would be to go public (via an IPO). Another goal might be to be sold off through M&A if its business secures confidence from the business community.

Japanese giants Toyota, Panasonic, Sony, and Honda were founded less than 100 years ago, all starting as small startups. Nowadays, few startups exist in Japan with the potential to grow into such giants. To remedy this situation, the Japanese government is placing priority on setting up startups.

2. Overview of University-Launched Startups in Japan

The Approved TLO System of 1988 has provided universities with a structure for providing their research results outside the campus. The Japanese version of the Bayh-Dole Act of 1999 has transferred from the country to universities the ownership

of rights to inventions they create through research with government-granted competitive funds. The Industrial Technology Enhancement Act of 2000 has allowed university teachers to jointly hold positions of a company officer outside of their university. In 2001, along this series of university reforms, Mr. Takeo Hiranuma, then METI Minister, put forward the “Hiranuma Plan,” geared toward encouraging universities to launch 1000 startups in three years. As a result, more than 1000 university-launched startups came into being. In 2006, however, an investment scandal occurred, cooling investor sentiment and making investors pull out of investing in startups. Consequently, enthusiasm for entrepreneurship, and many university-launched startups went bankrupt. In addition, no startups went public as the economy worsened. Startups eventually slowed to a crawl in a long period of winter-like hardship. Subsequently, administrative changes have occurred, and as the economy has been recovering, university-launched startups have started to go public.

The following are three examples of university-launched startups. V-Cube and Human Metabolome Technologies (HMT), both startups launched at Keio University, were listed on the Tokyo Stock Exchange Mothers market in 2013.

3. Startup Examples

The first example is V-Cube, a student-launched startup that operates an IT-based business.

In 1998, Mr. Naoaki Mashita, president of V-Cube, established V-Cube Internet Limited Company, the forerunner of V-Cube, while studying a master’s degree course at Keio University Graduate School of Science and Technology. The applicant Keio University filed a patent application for and acquired rights to his invention, which provided the basis for the startup business. Later he graduated a master course of graduate school of science and technology, Keio University. In 2001, the company was converted into an incorporated company and, in 2002, changed its name to V-cube Inc. In 2003, the company established affiliates, including V-cube USA, Inc. In 2006, however, V-cube Inc. and a group company integrated, specializing in visual communication services.

After that, the company expanded its branches (Malaysia in 2009, Osaka in 2011, Singapore and Indonesia in 2012, and Tianjin, China in 2013). In 2013, it went public on the Tokyo Stock Exchange Mothers market and in 2015, changed its stock listing to the First Section of the Tokyo Stock Exchange.

The company has held the top share in web conferencing services for eight consecutive years in Japan.

Venture-Example 1 V-CUBE

- 1998 V-cubing Internet LLC. established
- 2006 Merged into V-cube Inc., specializing in visual communication service
- 2015 Went public on First Section of TSE
- Main business: visual communication service



Mr. Naoaki Mashita
Inventor/Founder/
President



V-CUBE Meeting

Secure, Safe and High Quality
Holding top share for eight consecutive
years in Japan
High-quality cloud web conferencing service

<https://jp.vcube.com/>



The second example is Human Metabolome Technologies, Inc., a teacher-launched startup that operates life science business.


In 2001, Professor Tomoyoshi Soga at the Institute for Advanced Biosciences, Keio University, invented an anionic compound separation analysis method, and Keio University filed a patent application for the invention. This invention is the core technology for metabolome analysis using capillary electrophoresis mass spectrometry (CE-MS), which enables the simultaneous measurement of more than a thousand of metabolites (metabolome) present in a cell in a short time. It was patent-registered in 2002.

Based on this patented technology, Keio University Professor Masaru Tomita and Professor Tomoyoshi Soga jointly launched the startup HMT in 2003. Mr. Ryuji Kanno was later appointed as president from outside the university. This is a feature of a teacher-launched startup: the inventor does not hold the position of president to prevent systemic conflicts of interest from occurring (see 8.1 “Conflict of Interest”).

The company is an R&D-based startup that operates metabolomics business, focusing on three core areas: (i) contract analysis, (ii) biomarker discovery, and (iii) metabolome solutions.

In 2013, the company went public on the Tokyo Stock Exchange Mothers market.

Venture-Example 2

 **Human Metabolome Technologies**

- **Business:** Metabolome profiling, Biomarker Discovery , CE-MS consulting
- **Technology:** Identify more than 1,000 species of metabolites by the metabolome analysis technology using capillary electrophoresis mass spectrometry (CE-MS) developed by Dr.Soga
- **Founder:** Dr. Masaru Tomita
Dr. Tomoyoshi Soga
- **President:** Ryuji Kanno
- **Headquater:** Tsuruoka, Yamagata
- **Founded in** 2003
- **Listed in** 2013 at Tokyo Stock Exchange
- **Collaboration :** with the Institute for Advanced Biosciences (IAB), Keio University



Dr. Tomoyoshi Soga
Inventor/Founder



<http://humanmetabolome.com/>

The third example is Spiber Inc., an unlisted but promising life science startup launched by students.

This company has an innovative technology that synthesizes and mass-produces spider thread. Fiber material made from this thread is equal to steel in tension strength and flexible as rubber.

In 2007, a group of students launched Spiber. In 2008, the startup went into operation on Keio University's Yamagata Town Campus in Tsuruoka, Yamagata Prefecture.

In 2013, the startup succeeded in realizing mass production of synthetic spider thread and unveiled a blue dress made from it, as shown below. This was the first successful mass production of such thread in the world, an achievement that even NASA could not make.

In 2013, Spiber entered into a joint partnership with Kojima Industries Corporation, a Toyota business partner, for mass-production plant operation.

In 2015, Spiber concluded a business partnership with Goldwin Inc. and was funded total more than 9.5 billion yen including 3 billion yen from Goldwin, launching into commercialization products making use of synthetic spider silk material.

Venture-Example 3 Spiber Inc.



- **Technology:** producing synthetic spider silks by microbial fermentation and unique spinning technology
- **Headquater:** Tsuruoka, Yamagata
- **Founded in** 2007

Mr. Kazuhide Sekiyama
Inventor/ Founder/
President

Equal to steel in tensile strength. Flexible as nylon.



Dress made
from its synthetic
spider thread



The Wall Street Journal
July 10, 2013

<http://online.wsj.com/article/SB10001424127887324399404578583562603579062.html>

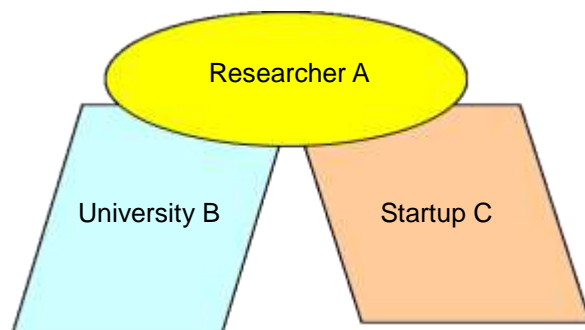


<http://www.spiber.jp/company/>

8. Conflict of Interest

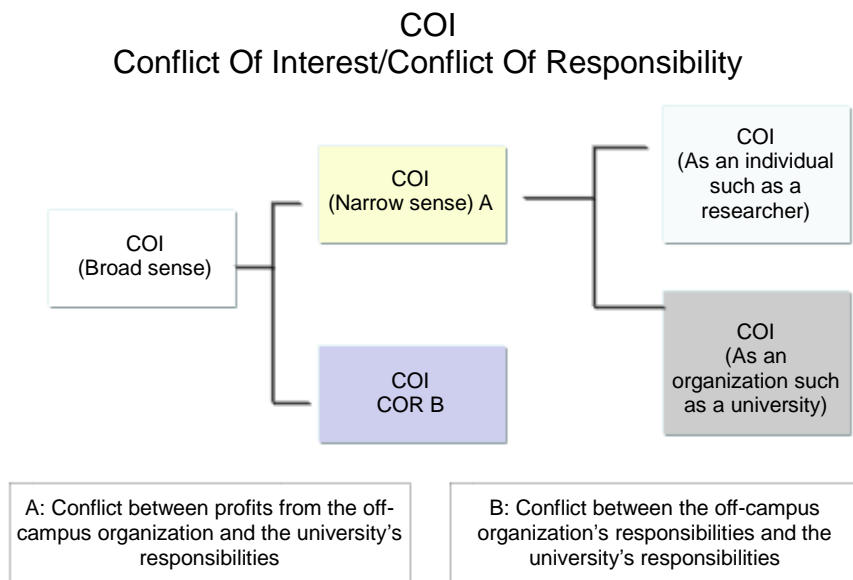
1. What is a Conflict of Interest?

A conflict of interest (COI) is an issue (collision of interest) that always arises, to one degree or another, when person A belongs to two organizations B and C, or more. Particular attention should be paid to COI issues especially when person A holds a position in each of the organizations that has decision-making authority on business policies and operations or whereby he/she may exert his/her influence on such decision-making. A COI, the appearance of which is sometimes treated the same as an actual COI, means a situation where Researcher A may be suspected by University B or Startup C of taking part in or being preferentially treated by the other organization. Therefore, a COI is not in itself a violation of law.



Narrowly defined COIs are collisions of interest, divided into individual COIs involving researchers and organizational COIs involving universities or other institutions. Of the two types of COIs, individual COIs should be managed with priority. Broadly defined COIs include conflicts of responsibility. A conflict of responsibility means a collision that occurs when one person performs

responsibilities at two organizations. For example, Researcher A, if serving as a University B teacher and a Startup C technical staff member, will be in a conflict of responsibility if no clear distinction is drawn between the researchers' working hours at Startup C and his/her working hours including class time at University B.



2. COI Examples

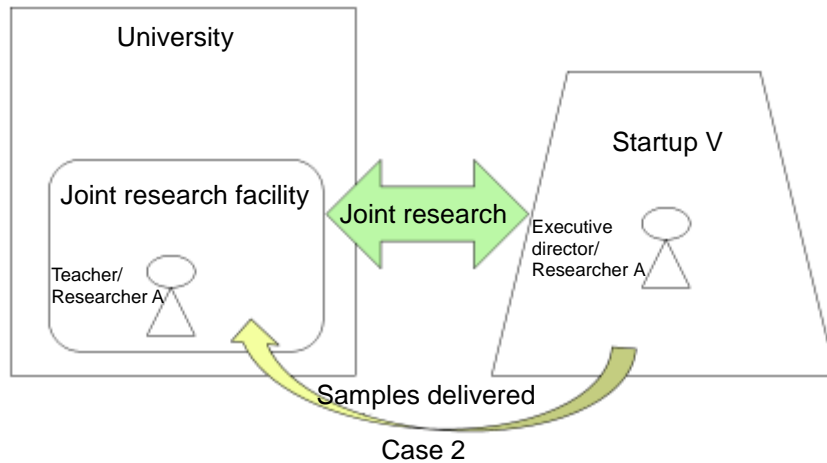
Case 1

- Researcher A, a university teacher, founds Startup V based on his research results.
- To commence operations as early as possible, the researcher thinks that he has no option but to become president himself, and submits a notice of startup and side business to the university's administrative bureau.
- After that, he rents a joint research facility on the university's campus to upgrade his research, starting joint research with Startup V.

To prevent COI concerns from arising under these circumstances, he should solve the problems and address the challenges listed below:

- Q. Can Researcher A, while serving as a teacher, assume the position of representative director of Startup V?
- Q. If not, what position is appropriate for Researcher A to hold?
- Q. To what matters should Researcher A pay attention to reconcile his/her duties at the university and at Startup V?
- Q. To what matters should Researcher A pay attention in conducting joint research with Startup V?

Case 1



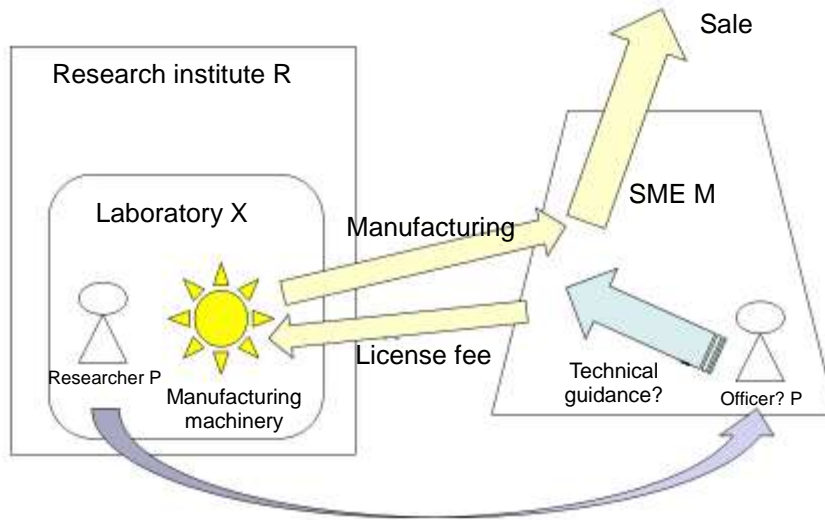
Case 2

- Startup V operates a business that has been developed from said Researcher A's research, preparing and selling test samples for use in the fields of research.
 - Researcher A places an order with Startup V for test samples for university research, thinking the least risky and most convenient method of pursuing research would be to purchase samples from the company.
- Q. Is there any problem in Researcher A ordering test samples from Startup V?
- Q. What kind of relationship should there be between the ordering organization on the university's side and Researcher A?

Case 3

- Laboratory X of Research Institution R has one of only a few high-value production machines in Japan.
 - Small Business M finds it is possible to manufacture and sell products at high volume and low price using this machine.
 - Small Business M approaches Laboratory X to request the use of the machine in return for payment of a prescribed usage charge.
 - After that, Small Business M requests Researcher P of Laboratory X to join the company as an executive officer to give technical guidance.
- Q. How should the university's COI management committee deal with this situation?

Case 3



3. COI Management

Universities should build up a functional COI management structure by developing a COI management policy and setting up a COI management committee and its secretariat. COI management policy may vary by university. There are three focal points of COI management: (i) ensuring transparency (self-reported information disclosure), (ii) ensuring accountability (interviews and hearings), and (iii) encouraging both the reporter and the committee to have a cooperative “thinking-together” attitude.

(1) Self-reported information disclosure:

Disclosure here does not mean opening to the general public but rather disclosing by reporting to the COI management committee. If any of the events listed below occur, the university researcher will promptly report the matter to the secretariat. Researchers should report to the secretariat on a regular basis, for example, once or twice a year, regardless of whether or not any of the following events occur. The secretariat will keep confidential and appropriately manage reported information. It does not need to disclose reported information to the public. Management means identifying and applying an appropriate way of handling such information by reference to past cases if any of the following events occur.

- A joint research/contract research/licensing agreement is signed
- A person starts to jointly hold a position as a director, etc.
- A startup is founded

(2) Interview and hearing:

Reporters have accountability to society (third parties). Depending on the information reported, the IOC management committee will interview and hear

findings from the reporter to understand the details of the status of COI. Depending on the status of COI, the committee will, if it deems it problematic, consider in consultation with the reporter about a workaround by changing or discontinuing the plan. Meanwhile, if the committee deems that the status does not present any problems, the COI status does not need to be worked around. The status should be kept transparent by ensuring periodic information disclosure through (i) interviews and hearings in (ii) above. Evaluation standards regarding the method to be employed vary by university according to COI management policy. The COI management committee takes charge of decision-making, and the university takes final responsibility for the decisions made.

9. Expectations of Universities in Innovation Creation

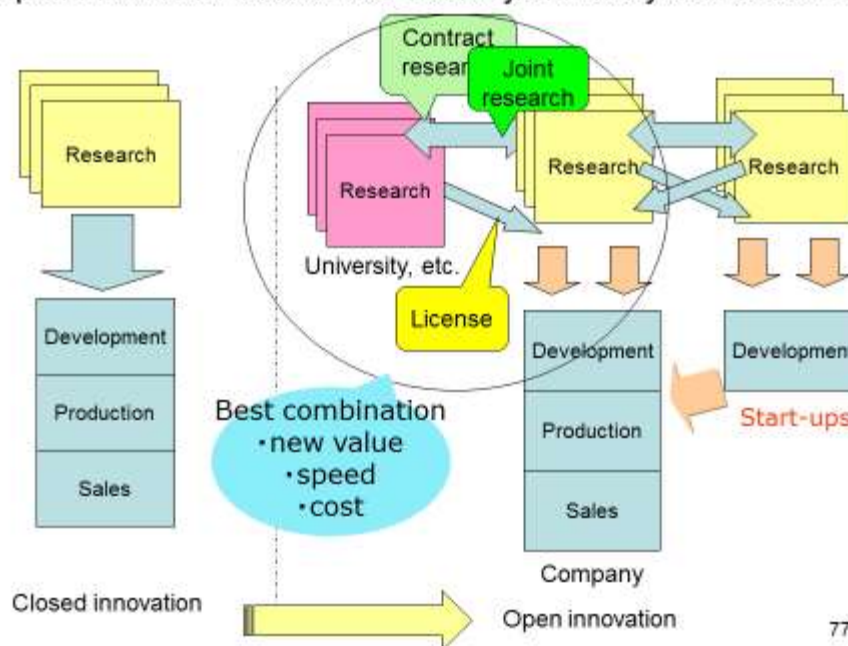
1. Toward a World of Open Innovation

Today people around the world can easily communicate via the Internet. As a result, communication is becoming more robust while competition is heating up globally. Amid this global mega-competition, the ability to manufacture new valuable products early and at low cost decides the outcome. In 2004, Mr. Henry Chesbrough, then professor of Harvard Business School, published *Open Innovation: The New Imperative for Creating and Profiting from Technology*, in which he proposes a new concept called “open innovation” as a mechanism to compete effectively.

The antonym of open innovation is “closed innovation.” Big companies so far have carried out in-house all processes from basic research through product sales. To that end, the companies have operated their own large basic research centers with many researchers. In open innovation, however, manufacturing companies do not need to have a total basic research center. They may instead team up with universities and research institutions around the world, he says.

This will generate a new task of finding out an appropriate partner and negotiating for a contract. If successful, however, this will have the potential to bring three advantages: (i) new valuation creation, (ii) speedup, and (iii) cost reduction. (i) New value creation refers to the creation of novel ideas and values through collaboration between two organizations with completely different values and beliefs, such as in the case of joint research and technology transfer between industry and academia. (ii) Speedup refers to the fact that if a university anywhere in the world has created a new technological “seed” as a research result that the company wants, the company can significantly cut the seed development time by bringing the result into itself, specifically, by receiving a license from that university. Alternately, if what the company wants does not yet exist, the company may conduct joint research with a university or research institution, if any, that has the potential to develop it. Either option can cut not only R&D time but also in-house basic research personnel, leading to (iii) cost reduction. However, it would be dangerous for the company to outsource R&D completely, reducing all of its research personnel. To create the expected effects from such a partnership, it should have an appropriate number of researchers in-house. The company should keep in mind that it needs to have a structure that includes specialists who can evaluate the quality and reliability of the research results from the partner university or research institution in accordance with the company’s requirements.

Open Innovation accelerates industry/university collaboration.



77

2. Technology Transfer, University-Industry Collaboration, and URA Training

The above sections have explained the importance of the ways in which university research results are exploited for social development. However, it is not easy to take advantage of such research results. This is largely because university-generated technologies may be high risk. As described in 7.1 “Why Are Startups Necessary?” university research results may be novel but are nonetheless high risk. Negotiators on the side of existing companies in Japan do not want to take this risk without failure. Their attitude is understandable since failures are often viewed negatively in Japan, resulting in discreditation.

Why are university technologies high risk? One reason would be that university research results come from basic research that has quite a long way to go to achieve commercialization, with many difficulties likely to arise en route. Another reason would be that the research results obtained are merely best resulting data with low reproducibility. In some cases, no prototype may be available.

In 1988, therefore, the Japanese government introduced the Approved TLO System to facilitate the setting up of a TTO or TLO at universities as an expert organization serving as a bridge between industry and academia to reduce risks such as those mentioned above. However, simply setting up an organization does not ensure that everything will go well. At first, many TTOs/TLOs employed technical experts near retirement age who had worked in corporate intellectual property, R&D or new business departments. Of these experts, some produced successful results, but many had trouble familiarizing themselves with their new jobs. In addition, the TTOs/TLOs needed to nurture the younger generations to shoulder the future of their organization.

It became important therefore for the country as a whole to nurture experts who

could serve as a bridge between universities and companies: specifically, technology transfer managers, licensing associates, and university-industry collaboration coordinators (collectively “university-industry coordinators”).

What skills do university-industry coordinators need? In 2014, 15 years after the introduction of the Approved TLO System in Japan, the incorporated administrative agency, the Japan Science and Technology Agency (JST), entrusted the general incorporated association, the University Network for Innovation and Technology Transfer (UNITT), to conduct a questionnaire survey of university-industry coordinators on the necessary skills that they must possess. In response to the survey, university-industry coordinators of 70 universities and 12 TTOs/TLOs across the country answered that they needed: first, network-building skills, second, communication skills, and third, technological seed exploration and evaluation skills. The survey found that network building and communication skills were more highly needed on site than skills to explore and evaluate marketable technological seeds. In other words, university-industry coordinators were required, among other things, to be able to explain matters accurately to appropriate persons at partner or prospective partner companies whom they encountered through business networking.

In addition to expert training for technology transfer and university-industry collaboration, MEXT started in 2011 to develop research management human resources called “university research administrators” (URAs). The purpose was to reduce the time researchers spent on non-research activities by developing a structure that enabled researchers to focus their energy on their research. The URA’s duties may mainly include (i) supporting research strategy development, (ii) supporting external funding acquisition (pre-award), and (iii) supporting research project implementation (post-award; including the management of intellectual property and other research results). Since the duties overlap some of the duties of university-industry coordinators trained thus far, cross-functional human resource development is currently under way, including network building, without distinguishing between technology transfer experts, university-industry collaboration experts, and URAs.

http://www.mext.go.jp/a_menu/jinzai/ura/index.htm [Japanese text only]

3. Network Building and Specialist Training

This section introduces two initiatives that Japan takes to develop human resources in technology transfer and university-industry collaboration.

(1) University Network for Innovation and Technology Transfer (UNITT)

<http://unitt.jp/en>

UNITT, established as “Council of TLO” in 2000, is known as Japan’s version of the Association of University Technology Managers (AUTM). Its membership consists of 43 universities, including major universities, 22 TTOs and TLOs, and four public research institutions in Japan. Although it also has individual associate members, UNITT is basically an organization of corporate members. UNITT’s annual conference, which has been held for more than 12 years, is a two-day meeting that provides the opportunity for discussion in a five- or six-track workshop. At the conference reception, participants engage actively in network building and information exchange. This may be the largest event of its kind in Japan, attracting around 500 persons involved in technology transfer

and university-industry collaboration from universities across the country.

UNITT also organizes basic and applied small group training courses, respectively, for technology transfer experts, twice a year.

It's one of the world issues to develop a human resource for the technology transfer. ATTP^{note1}, international training program, is promoting to certify RTTP^{note2}, international technology transfer professional world wide.

UNITT joined ATTP in 2013, therefore a member of UNITT has had a qualification to apply for the registration of RTTP since then. UNITT expects many international technology transfer professionals will grow through getting RTTP.

(※1) ATTP: Alliance of Technology Transfer Professionals

(※2) RTTP: Registered Technology Transfer Professional

- Network for technology transfer and
industry/university collaboration -UNITT-**
- (1) What is UNITT?
"University Network for Innovation and Technology Transfer", "AUTM Japan"
- (2) Membership
43 universities, 22 TLOs and 4 public research institutes
- (3) Program for development of TT experts and coordinators
- ✓ Annual conference: ① Two days training program ② More than 500 people are all together ③ Continued for 11 years
 - ✓ Training Program for TT experts:
① twice a year ② Basic / Applied course



(2) JST Training Program for Technology Transfer Specialists

<http://www.jst.go.jp/tt/mekiki/> [Japanese text only]

With support from MEXT, JST started the training program for technology transfer specialists in 2002. Technology transfer specialists are referred to as human resources engaged in technology transfer and university-industry collaboration activities to put the research results of universities and other research institutions to practical application. This program provides training aimed at improving expertise and developing a network of technology transfer specialists.

Technology transfer licensing specialists are expected to create a new value

through the activity of combining technical seeds, market needs, intellectual properties, research/development resources among academia and industries strategically.

This program has attracted a cumulative total of about 8,000 participants over 14 years. The program consists of four annual training courses and one-day agreement practice course. The former four courses are ① the practical project management course (eight days a year; limited to 15 participants) ② the basic coordinate course (four days a year; limited to 40 participants) and ③ the research support management course (four days a year; limited to 40 participants such as clerical stuffs of a university and so on). JST gives a certificate to the trainee who completed one of these three training courses.

The latter one-day course is limited to 20 participants. With less than half of the time spent on classroom lectures, each course provides training in a small-group discussion style, focusing on improvement of communication skills and network building.

Training program for technology transfer and industry/university collaboration experts -JST-

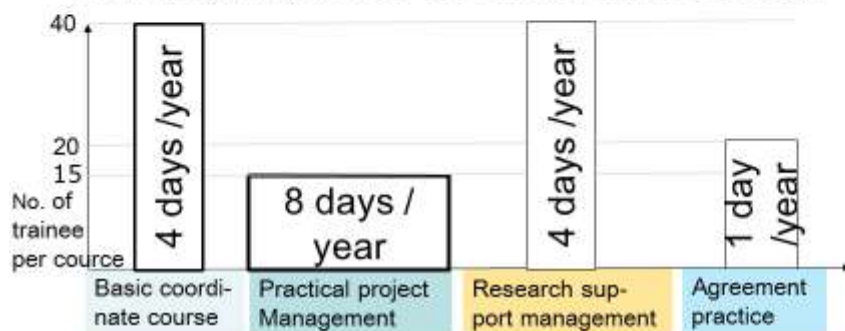
1. Who is trained?

- Coordinators for academia-industry collaboration
- Clerical staffs for this office

2. How many years? How many people?

- More than 13 years
- More than 8,000 people have been trained

3. Training programs for coordinator and clerical staff





10. Appendix

1. Japanese Government Bodies for Technology Transfer, University-Industry Collaboration, and Human Resources Development

- (1) University-Industry Collaboration & Regional R&D Policy Division, Science and Technology Policy Bureau, MEXT

http://www.mext.go.jp/a_menu/02_f.htm [Japanese text only]

This division is responsible for measures relating to universities' collaboration with industry and government, and technology transfer, as a government body promoting the third university mission, "social contribution."

- (2) Industry-University Collaboration Office, Industrial Science and Technology Policy and Environment Bureau, METI

http://www.meti.go.jp/policy/innovation_corp/top-page.html [Japanese text only]

This office is responsible for measures for university-industry-government collaboration and technology transfer, as a government body developing Japanese industry through promoting university-industry cooperative activities such as university-industry collaboration and technology transfer.

- (3) Foreign Advisory Unit, International Cooperation Division, Policy Planning and Coordination Department, JPO, METI

https://www.jpo.go.jp/torikumi/kokusai/kokusai2/training_program15.htm [Japanese text only]

The web page above introduces this program as described below.

"The JPO supports initiatives for establishing an intellectual creation cycle in developing countries, thereby promoting the development of an intellectual property system in developing countries and self-sustained growth of their economies to eventually contribute to the sustainable growth of the global economy. Beginning in 1996, the JPO has actively supported human resource development for reinforcing intellectual property protection in the developing world by inviting and training trainees from developing countries, mainly in the Asia-Pacific region."

- (4) Asia-Pacific Industrial Property Center (APIC), Japan Institute for Promoting Invention and Innovation (JIII)

<http://www.training-jpo.go.jp/en/index.php/37>

APIC provides cooperation in human resources development in intellectual property rights in the Asia-Pacific region through the IPR human resources development cooperation program entrusted by the JPO.

- (5) Japan Science and Technology Agency (JST)

- (i) Training Program for Technology Transfer Specialists

<http://www.jst.go.jp/tt/mekiki/> [Japanese text only]

Receiving MEXT support, JST provides the program for training aimed at improving expertise and developing a network of technology transfer specialists, who are engaged in technology transfer and university-industry collaboration activities to put the research results of universities and other research institutions to practical application. See (2) of 9.3 “Network Building and Specialist Training.”

(ii) Foreign patent filing support

http://www.jst.go.jp/chizai/pat/p_s_01boshu.html [Japanese text only]

The research results of universities and other academic institutions take a dozen or so years of licensing to generate significant license fee income, partly because the results are basic (according to the experience of US universities). Therefore, the IP management division has become a cost center for many universities, with its economic position becoming fragile. Meanwhile, foreign applications are highly costly. From a national policy point of view, the Japan Science and Technology Agency (JST) has established a system for loaning for filing foreign applications that fulfill certain conditions. See 4.3 “Use of National Support for Foreign Applications.”

2. University-Industry Collaboration and Technology Transfer Networks and Associations in Japan

(1) University Network for Innovation and Technology Transfer (UNITT)

<http://unitt.jp/en>

After the Approved TLO System came into effect in 1998, UNITT was founded in 2001. It is also known as Japan’s version of the Association of University Technology Managers (AUTM). UNITT’s membership consists of 43 universities, including major universities, 22 TTOs and TLOs, and four public research institutions in Japan. Although it also has individual associate members, UNITT is basically an organization of corporate members.

(2) Intellectual Property Association of Japan

<http://www.ipaj.org/aboutus/index.html>

The web page above introduces this program as described below. This association was established in 2002. The membership is not limited to engineers and researchers who create intellectual property. The association also includes a wide range of individual members who are interested in intellectual property studies in the fields of law, economics, and sociology. Unlike UNITT mentioned in (1) above, which consists of task forces for technology transfer and university-industry collaboration, the association focuses on intellectual property research.

“To promote needs-oriented intellectual studies, the Intellectual Property Association of Japan (IPAJ) was founded in October 2002 by researchers who were the creators of intellectual property, and corporate managers who were their main users.

Members from a broad range of intellectual property fields were brought

together to facilitate research activities in interdisciplinary studies, such as science and technology, management, law, and economics, for science and technology as well as for the creation, protection and exploitation of contents.”

(3) Japan Society for Intellectual Production

<http://www.j-sip.org/>

The web page above introduces the purpose of this society as described below. This society was established in 2005. The membership consists of any individuals who are interested in university-industry collaboration. Unlike UNITT mentioned in (1) above, which consists of task forces for technology transfer and university-industry collaboration, the academic society focuses on activities such as research presentation/publication and case studies.

“JSIP is committed to educating all individuals interested in university-industry collaboration to raise their level of competency in engaging in such collaboration, to conducting comprehensive support projects for regional university-industry collaboration activities, and to upgrading university-industry collaboration work to a professional specialty occupation.

Through such activities, JSIP aims to establish an academic discipline of university-industry collaboration and develop university-industry collaborations themselves, thereby promoting scientific and technological development in Japan and contributing to social development that helps local communities conduct activities, using local advantages to enhance local characteristics and vitality.”

3. Related Provisions of Patent Laws

(1) Article 73 (Jointly owned patent rights), Patent Act

Article 73

1. Where a patent right is jointly owned, no joint owner may assign or establish a right of pledge on said joint owner’s own share without the consent of all the other joint owners.
2. Where a patent right is jointly owned, unless otherwise agreed upon by contract, each of the joint owners of the patent right may work the patented invention without the consent of the other joint owners.
3. Where a patent right is jointly owned, no joint owner may grant an exclusive license or non-exclusive license with regard to the patent right to any third party without the consent of all the other joint owners.

(2) Patent Laws U.S.C. 262

Patent Laws U.S.C. 262 Joint owners

In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.

(Amended Dec. 8, 1994, Public Law 103-465, Sec. 533(b)(3), 108 Stat. 4989.)

- (3) Article 15, Patent Law of the People's Republic of China (Effective October 1, 2009)

If there are agreements regarding the exercise of rights by the co-owners of the right to apply for the patent or of the patent right, the agreements shall prevail. In the absence of such agreements, the co-owners may separately exploit the patent or may, in an ordinary manner, permit others to exploit said patent. Where others are allowed to exploit the patent, the royalties received shall be distributed among the co-owners.

Except under the circumstances specified in the preceding paragraph, the exercise of the co-owned right to apply for a patent or of the co-owned patent right shall be subject to the consent of all the co-owners.