

## Current Status and Proposals on Protection of Universities' Patents in Life Science

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### Abstract

Life science industries owe much to research and discoveries in universities. Here we focus on life science and discuss issues that are typical of patent applications at universities.

### 1. Current Situation of Patent Applications at Universities

In order to improve the sluggish economic conditions of Japan from the beginning of the 1990s, the government formulated policies from the second half of the 1990s to promote the use of research results from universities, and enacted the "Act on the Promotion of Technology Transfer from Universities to Private Business Operators" and then the "Act on Special Measures for Industrial Revitalization", the so-called Japanese version of the Bayh-Dole Act. Corporatization of Japanese national universities in 2004 and setting up the intellectual property organization in many universities have resulted in substantial increase in patent application by universities after 2004. In 2008, the number of patent applications made by national universities has risen to 9,435, which was about a four-fold increase compared with that in 2003.<sup>1</sup> The life science is the field that received the biggest number of applications, which accounted for 34% of the total applications.

Last year, we made a survey for interest of industries in the first stage in drug discovery research activities in universities by presenting mock patents such as those for therapeutic antibodies, nucleic acid agents and low-molecular weight compounds. The survey showed a high possibility that a large pharmaceutical company is willing to use a license of such a university patent even at an initial stage.<sup>2</sup> We presume that this reflects the high contribution by basic university research in life science to intellectual property in biotechnology and pharmaceuticals.

Kyoto University received 405 declarations of invention during 2008. Patent applications here are being actively pursued, and consist of 227 domestic applications and 207 foreign applications.<sup>3</sup> Among them, there is a patent that may have a large impact on the society such as the iPS cell (induced pluripotent stem cell). Income from intellectual property steadily increased from ¥ 17 million in 2004. Income from patent licensing rose to approximately ¥48 million,

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and when other licensing income such as research materials is combined the total becomes ¥102 million in 2008 compared to ¥ 55 million in 2007.<sup>3</sup> All activities of industry-academia-government collaboration and patent applications in Kyoto University is conducted by the Innovative Collaboration Center, which carries out its activities separately in four areas of different academic fields, that is, “Physical, Engineering and Agricultural Sciences”, “Software and Contents,” “Medical and Biotechnology (Biological Sciences)” and one devoted to intellectual property for “iPS Cell Research”. The Medical and Biotechnology Division is responsible for activities in the life science field, and manages intellectual properties and collaboration between academia, government and industry focusing on life science. One of the academia-industry collaborations the Medical and Biotechnology Division are managing is the “Center for Innovation in Immunoregulative Technology and Therapeutics” so called the Astellas-Kyoto University Project.<sup>4</sup> This project abbreviated as the A-K project is a large scale industry-university alliance for drug discovery that is performed in the Graduate School of Medicine. An intellectual property committee has been established within the project and has received transfer of authority from the Innovative Collaboration Center for determination of matters related to intellectual property including patent applications there. An intellectual property management office is within the site of the project with specialist staffs and is engaged actively in identification of inventions, management and protection of intellectual property. Kyoto University has thus adopted flexible actions to respond to individual requirements in intellectual property management in the life science.

However, through our experience of more than five years of managing intellectual properties in universities, we have also noticed problems in the patent quality and exploitation at universities. One problem is that university inventions have the lower level of exclusivity for patent applications than those by industry.<sup>5</sup> This situation is caused in part by less experience at universities regarding pharmaceutical patent applications, still insufficient knowledge of university researchers and a shortage of suitable personnel to carry out management of intellectual property. However, training university scientists in intellectual property or fostering appropriate human resources alone do not overcome the above problem, because these points do not constitute all the problems associated with university patents.

In this article, we focus on life science, extract and identify other problems associated with protection of patents from universities and propose support systems and legal provisions required for breakthrough.

## **2. Appropriateness of “Examples”**

The Examination Guideline<sup>6</sup> at the Japan Patent Office (JPO) states that “A medicinal invention resides in technical field where it is generally difficult to infer how to make and use a material on the basis of its structure and its name”. It requires a description of “Examples” to support the scope of the patent claims in pharmaceutical patents and the quality and the extent of coverage of “Examples” presented can affect the exclusivity of the patent.

However, substance patents for synthetic compounds applied by universities present substantially less “Examples” of the compounds than those of the application by pharmaceutical companies,<sup>7</sup> and more than one half of

the use-patent applications we reviewed presented an example of using only one compound.<sup>8</sup> Furthermore, universities are actively pursuing research of regenerative medicine and make numerous patent applications in that field. However, although cells used in actual therapies should be human cells, the inventions in this area are often applied by using data of murine cells as “Examples”. It is unclear in biotech areas whether rights of patents based only on “Examples” using murine cells will cover the use of human cells in clinics.<sup>9</sup> Furthermore, at the stage of actually licensing, pharmaceutical companies ask not only *in vitro*<sup>10</sup> results but also *in vivo*<sup>11</sup> results to judge the potential of this patent. Thus, enriching “Examples” in university patents is required in the life science area in order to increase the exclusivity and facilitate licensing to companies.

The question is how to solve this problem. We conducted a research to examine correlation of the number of compounds in a patent claim with the impact factor<sup>12</sup> of a journal in which academic papers related to that particular patent application were published and their number of citation, and found no correlation.<sup>13</sup> Given that publication is the first priority to most academia people, these results suggest that taking time to synthesize a large number of similar compounds for increase of “Examples” is not very attractive in academia. In other words, it can be said that a patent application does not function as a sufficient incentive for a university researcher to produce experimental data enough for this purpose. Furthermore, there are substantial problems that conducting additional experiments of low academic significance for the purpose of a patent application has large burden on students or graduate students who perform a majority of research work in Japanese universities.

Thus, one way to secure sufficient exclusivity and expand possibilities for licensing of university patents is for the university to provide funds and personnel for supplementing required “Examples”. Our survey above has disclosed that more “Examples” were described in joint applications than in sole applications by university in both substance- and use-patents, and the largest number of “Examples” in patent applications in joint application with private companies in substance patents.<sup>14</sup> We therefore suggest that joint research with companies is a useful strategy for enriching “Examples”. When the industry partner requests the addition of “Examples” to an invention in the joint research in a case that further experiments impose a large burden and little scientific significance to university researchers, one solution is the employment of external technical staff. It is therefore hoped that a partner industry in joint research understands the costs required for employment of technical staff for that purpose. Furthermore, “Examples” can be increased in joint research among academics by collaboration of researchers of different expertise, having technical or research materials required for acquiring additional data. An example is collaboration of researches possessing compounds and those measuring their activity. Thus, the quality of university patent application can be improved if the databases of techniques or research materials held by individual researchers are constructed and further facilitate joint research among academics. There is also another possible measure that enrichment of “Examples” can be achieved by improving patent application and publication management as discussed later.

### 3. Costs of Foreign Applications

The majority of pharmaceutical companies developing novel medicines sell their products on a global basis by itself or through sales partnership with Japan, Europe and the United States as major markets. The rate of foreign applications is therefore high in comparison with other industries and the rate of applications to the United States in the pharmaceutical industry is 42% of their total inventions.<sup>15</sup> Furthermore, recognition of the companies' activity by making foreign applications can increase its opportunity for cooperation with companies in Europe and the United States. It is therefore important for university patents on pharmaceuticals and their licensing activities whether their application is filed in Europe and the United States.

Foreign application requires additional costs to domestic application. For example, if an application of 50 pages with 12 claims is applied under the PCT (Patent Cooperation Treaty), the cost is estimated approximately ¥500,000<sup>16</sup>. Since the number of pages in a specification for inventions related to pharmaceuticals is usually higher, the costs are normally ¥700,000 - ¥800,000. Furthermore, at the stage of application in individual countries, further costs are incurred, for example, for the translation of the specification. Consequently, large costs are required for applications to the trilateral patent offices of Japan, Europe and the United States that are the main markets for pharmaceutical companies.

Since universities cannot afford money to cover the costs of foreign application, they require external support for foreign applications for university patents. The Japan Science and Technology Agency (JST) provides the main support for foreign applications of university patents.<sup>17</sup> This system supports costs the filing of a PCT application, application in individual countries after a PCT filing, and covers costs necessary for application including application fees and examination fees to granting of rights. The rate of receiving support from JST has, however, decreased year by year, because, in the absence of other supporting system, JST received more than 100 support applications per month in 2009, which far exceed the number of support it affords.

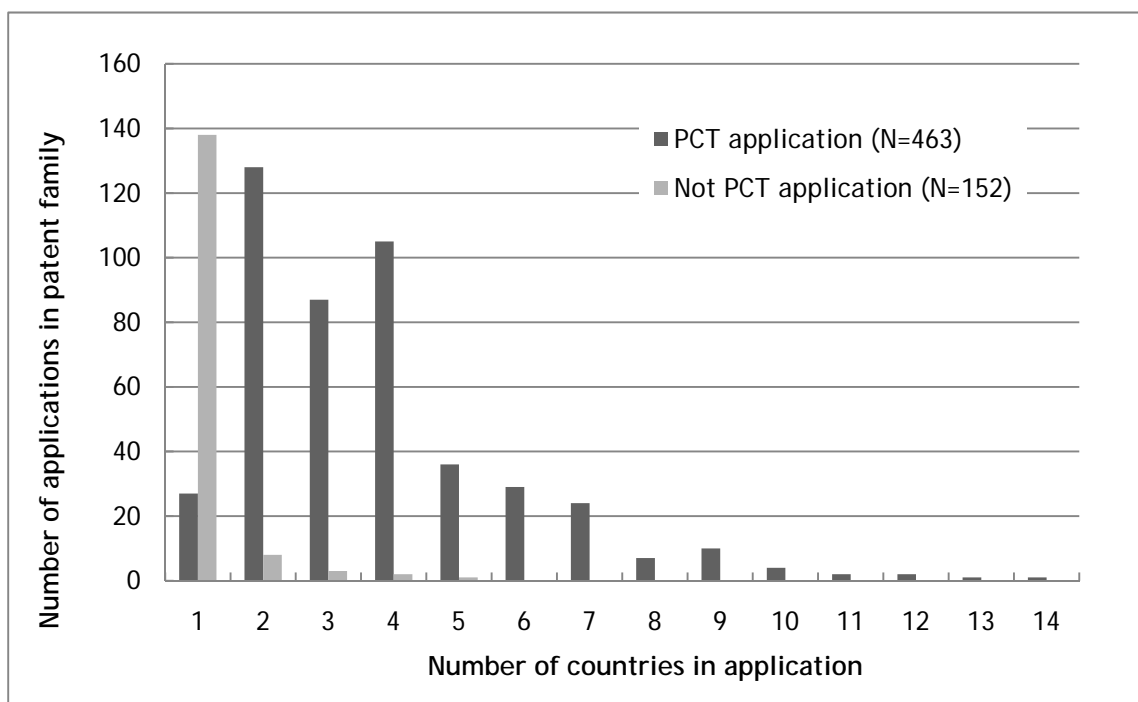
The proportion of foreign applications of the total university patent applications was 30% in 2007.<sup>18</sup> However, the proportion of invention actually forming the subject of a foreign application is approximately half the above figure, because the above figure was obtained by calculating the number of foreign applications on the basis of application in each country even of the same invention. Since more than half of the inventions in universities subjected to a PCT application or foreign application are joint patents<sup>19</sup>, it is surmised that the number of foreign patents by a university alone is smaller.

We have taken as an example the regenerative medicine area that is one of the fields with a high proportion of applicants belonging to universities and public research institutions, and analyzed foreign application in this area. The 2008 report<sup>20</sup> from the Japan Patent Office pointed out that far less numbers of international applications were made by Japanese scientists in this area those scientists of other nationalities. Our survey on world-wide applications on stem cell technology with priority dates in 2001 demonstrates a large difference in the number of countries covered by an

application depending on whether it was subjected to PCT application. Ninety-one % of inventions associated with patent families that were not PCT applications were filed only in a single country. In contrast, patent families subjected to PCT application were applied in 3.8 countries on average (See Figure 1).<sup>21</sup> The PCT application proportion of non-profit U.S. institutions was 86% and 100% for non-profit EU institutions. In contrast, the PCT application proportion of non-profit Japanese institutions was 52%.<sup>22</sup>

Thus, there is currently insufficient number of foreign applications made by sole applications of universities. Insufficient funds available likely deprives many patents of an opportunity for PCT application within one year after the domestic application. On a PCT application, the applicant can claim to priority and add “Examples” more relevant to clinical application to increase a possibility for licensing. However, under the current support system, applications for support for foreign application must be submitted to JST within 6 months after the domestic application. It is often difficult to obtain in this short period enough materials for proper evaluation, and many potentially important patents fail to receive the JST support for PCT application. We therefore suggest that increasing support for PCT application enhances better use of university patents, allowing addition of required data, widening opportunity for foreign applications and more efforts for licensing.

**Figure 1: Number of Countries in Application for PCT/Not PCT in Areas related to Stem Cells**



During application in individual countries after the PCT application, costs required are further increased, for example, by costs for translation or handling fees of local agents. Many pharmaceutical companies usually demand application in a number of foreign countries for licensing.<sup>23</sup> It is difficult for universities to afford such costs. Selection

of designated countries depends on markets of products and business regions of companies for licensing. It is therefore recommended that the university should find a business partner before application in individual foreign countries to obtain financial and personnel support for costs and handling.

Foreign applications thus require not only a large cost of money but also large time and efforts of staffs in technology transfer office (TTO) of universities handling those procedures. To make use of limited human resources, the university better avoids an unnecessary increase in the number of patent applications. Sufficient care can be paid to necessary foreign applications when we focus on patent applications that are useful for business.

#### **4. Management of Patent Applications and Publication**

##### **(1) Current Situation of Management of Patent Applications and Publication by Universities**

Research results at universities must be made known to society by presentation at academic meetings or publication of academic papers. Consequently, in contrast to the management of patent applications at private companies, the management of patent applications at universities should be coordinated with publication. Quite often, inventions at universities are not applied for patents before publication. Art. 30 of the Patent Law is applied to those applications, and saves them from the loss of novelty by the provisions of application within 6 months after the publication (hereafter “application of Art. 30”). Analysis by Tanaka and Aono of patent application for inventions of pharmaceuticals shows that no application was made under Art. 30 for a substance patent by pharmaceutical companies, while 32% of applications by universities was made under an application of Art. 30.<sup>24</sup> Our analysis on pharmaceutical patent application has also revealed that the number of compounds used in “Examples” is lower in applications made pursuant to the application of Art. 30 than applications to which Art. 30 is not applied.<sup>25</sup> Therefore, patent applications subject to an application of Art. 30 have apparently lower level of exclusivity, because thoroughness of “Examples” generally strengthens exclusivity in a pharmaceutical patent, as we discussed above. Additionally, since an exception by application of Art. 30 is given only to presentations at academic societies in Japan designated in the Law<sup>26</sup>, it does not cover presentations at oversea meetings. Further, since an application under Art. 30 is valid only under the laws of Japan, presentation and publication of inventions leads to loss of opportunities for patent application in all countries except the United States that allows application within one year after presentation. This situation can be improved by several ways. On one hand, it is imperative that TTO staffs of universities coordinate scheduling of patent applications and publication. Those staffs can keep close contact with researchers and instruct them to take scheduling of patent application into account and submit an invention report in time. However, we think it more important to introduce a system to coordinate publication and patent application in a more relaxed way. Below, we propose introduction of a provisional application system and amendment to the standards for approval under application of Art. 30.

##### **(2) Proposal for introduction of a Provisional Application System**

One initiative under the “Intellectual Property Strategic Program 2009” was to strengthen the function of the TTO or the university intellectual property headquarters by the introduction of a mechanism that requires university researchers to review the possibility of filing patent applications before preparing a manuscript of relevant research papers.<sup>27</sup> However, our survey has revealed that researchers more commonly present their inventions first at various academic meetings; the majority of inventions subjected to application under Art. 30 were initially presented at academic societies.<sup>28</sup> Consequently, TTO staffs should be more alert to presentations at various society meetings than publication of papers in journals.

However, unlike publication by paper, there is a definite deadline for submission of an abstract for presentation at an academic meeting, and abstracts for many meetings are now publicly disclosed on-line far in advance of the commencement of the meetings. Furthermore, there are several meetings in life science such as the annual meeting of the Molecular Biology Society of Japan in which more than 10,000 people participate, and those meeting are held mostly in spring and autumn. Given such a big number of abstracts that accumulate in a short and certain period of the year, it is impossible for TTO staffs of a university to review all the relevant abstracts. Furthermore, since the deadline for abstract submission is generally set approximately 6 months or so prior to the meeting, abstracts are often prepared in anticipation of obtaining sufficient data in time for the presentation at the meeting, leaving only a minimum of experimental data available for review by the TTO staffs. Considering these situations of the patent applications in universities, we suggest it essential to introduce and create a provisional application system in which tentative application can be made with submission of simple written materials and a minimum amount of experimental data.

Such provisional application system is already in operation in the United States. The provisional application in the United States is a partial application with only one specification and does not require claims or a declaration. Such applications are often made in the form of a manuscript of an unpublished paper. Since this provisional application system waives the formalities required for a normal patent application, efforts for preparation of a specification is minimized and time spent for application can be reduced. The applicant may make a formal application within one year from the date of the provisional application. Although the provisional application expires after one year irrespective of whether a formal application is made, applicants can obtain the effective application date for the formal application at their early stage of invention. Therefore, a provisional application system is an effective solution to enable both publication and patent application especially when time for preparation of application is limited by the deadline for abstract submission or the date of presentation.

In the United States where the provisional application system operates, approximately 70% of new applications made by universities are made through this system,<sup>29</sup> and TTO staffs of the university then spend their time to promote licensing activities or examine the commercial value of inventions.<sup>30</sup> This allows them a strategy to perform pre-marketing search of relevant invention, evaluate its market value through licensing actions, and pick up only inventions with high probability of licensing for formal application. In Japan without the provisional application system,

university TTO staffs cannot examine market values and licensing probability of inventions before formal application, and TTO staffs have to spend their time and effort for application of inventions that may not have market values and little opportunity for licensing. Neither, in universities, the staffs can perform promoting activities before application on confidential.

Therefore, we regard the provisional application system quite useful in Japanese universities like those in the United States as a means of performing pre-marketing search, promoting licensing, and finally choosing those inventions of possible market value for formal application.

From the above discussion, we conclude that a provisional application system has merits for a university not only with respect to coordination management of patent applications and publication, a unique problem of universities, but also with respect to effective utilization of inventions from universities. Nikkan Kogyo Shimbun reported on June 29, 2009, that the JPO initiated consideration for the introduction of a provisional application system.<sup>31</sup> We carefully follow this development with interest.

### **(3) Expansion of Application of Art. 30**

Since patent application according to Art. 30 loses possible patent application in foreign countries other than the United States as described above and can add less numbers of “Examples” due to the 6 month limit, it is desirable to file the patent application before publication. However, it is more important for a university researcher to be recognized in an academic society by making presentation or publication before others than spending time to make enough number of “Examples” for a patent application. It is particular so in very competitive research areas, which scientists put publication before patent application in priority. Furthermore, as a consequence of publication or presentation at academic meetings, private companies may be interested in research results that researchers themselves consider not applicable to business or a patent application, and discuss with the researchers on filing of a patent application after the presentation.

However, in order to be qualified for application of Art. 30, the venue for the publication must be societies designated by the Commissioner of the Patent Office.<sup>32</sup> A society hoping to be designated for application of Art. 30 is requested to make application to the Commissioner of the Patent Office<sup>33</sup> with the statute or a corresponding document as well as a journal published by the association attached.<sup>34</sup> However, some research associations in certain areas do not have the statute or a society journal. Furthermore, as we discussed earlier, none of overseas associations is designated by the Commissioner of the Patent Office. Thus, a presentation at overseas meetings cannot receive the benefit of Art. 30. On the other hand, since the impact of a presentation at an international meeting is usually higher than that at domestic ones, university researchers prefer presentations of their research results at overseas meetings. This is particularly true for research results they believe more important.

Then, how important is a society to be designated by the Commissioner of the Patent Office in order that Art. 30



is applied for presentation there? There are numerous presentations at numerous meetings either international or domestic. Information on many of those meetings and even the titles of presentations there can be obtained and corroborated by the use of the Internet.

We therefore suggest that societies receiving application of Art. 30 should be expanded beyond those currently designated by the Commissioner of the Patent Office to all the academic meetings either domestic or abroad. This expansion will make an avenue to application of Art.30 open to those research results that are presented at meetings abroad and in which a private company becomes interested as a result of such presentation, allowing future patent application at least in Japan and the United States.

There is another point of improvement in Art.30. As described above, one reason for the paucity of “Examples” in the patent application subjected to Art. 30 is a 6 months’ time-limit from publication to filing of an application. Recently publication of abstracts for many societies has become more rapid than used to be due to publication on-line in the Internet. Furthermore, given that one to two months of time is required for the preparation of a specification, 6 months is a very short period for thoroughly thought-out application. To improve the quality of patent application by universities, we therefore urge a period from publication to application subject to Art. 30 to be extended from the current period of 6 months to one year, the same period under the law of the United States.

## **5. Issues associated with Joint Applications**

The provisions of Art. 73 of the Patent Law define the handling of rights of joint patent; while the implementation of joint patents by one applicant is possible without the consent of the co-applicant<sup>35</sup>, the consent of the co-applicant is required for transfer<sup>36</sup> and licensing<sup>37</sup> to a third party. Since universities usually do not implement the patent rights, they cannot defray the costs associated with application without receiving income from transfer payments or licensing payments. When a joint application is filed, therefore, universities need financial conditions that the university (1) receives income from the joint applicant on implementation of the patent, (2) is not responsible for patent application costs, and (3) obtains income from licensing activities to third parties.

There is also an issue on the “non-implementation compensation”, which is a claim of a university for payment by the private company equivalent to non-working by the university. It has been the frequent subject of discussions between industry and universities. Through these discussions, universities have developed flexible responses, and one policy adopted by one university is that “the university asks payment when a patent is implemented exclusively by co-applicant industry, while the payment is waived when the patent is used non-exclusively, and in this case the university asks all the patent costs to be paid by the co-applicant company instead”.<sup>38</sup>

“Non-implementation compensation” is not a big issue in life science, because patent rights are usually implemented exclusively by pharmaceutical companies. However, problems often arise when executing Material Transfer Agreements (MTA), a particular type of contract in life science. Kyoto University Medical Science and

Business Liaison Organization<sup>39</sup> is dealing MTAs for Graduate School of Medicine and affiliated hospitals, and executes approximately 500 MTAs per annum<sup>40</sup>, some of which involve transfer of research materials from private companies. Our 2006 survey has found that when private companies provide research materials to a university, they request the attribution of an invention obtained by use of the research materials to be “joint”.<sup>41</sup> When the university succeeds to make an invention subject to such an MTA, it may cause a risk that only the company providing the materials may be the subject of a license, even when the conditions of joint patents is determined by joint application agreement at the time of application.

In order to solve current problems associated with joint application, a revision of Art. 73 of the Patent Law is required. If the provision of a license to a third party becomes possible without the consent of the joint applicant as in the United States, a risk of the invention being left without implementation can be avoided. When the joint applicant wants an exclusive license, conditions for exclusive licensing should be discussed and determined on joint application. Universities make the majority of inventions by using taxes of people and risks of mothballing the invention must be avoided.

## **6. Conclusion**

As we stated in the beginning, utilization of research results at universities has been extensively promoted by introduction and innovation of various systems of support as well as legal provisions and revisions. The application for patents by universities in Japan is undergoing rapid growth coupled with rapid growth in industry-academia-government collaborations. However, since universities are not entities implementing patents and have an important mission of publication of research results, there arise a range of problems specifically associated with university patents through their experience over the last 5 years.

In particular in life science, there is a problem how sufficient “Examples” can be incorporated into patent applications within limited resources of universities and with difficult coordination between patent application and publication, since rights in a pharmaceutical invention are determined by disclosed “Examples” in the patent. Furthermore, due to high demand for ensuring pharmaceutical patents overseas, there is also a problem of cost. As described in this article, there are several strategies to secure money for such cost such as closer collaboration with partner companies and selection of inventions with high probability of licensing. Additionally, we request more financial and human resources support for ensuring patent applications in life science.

More generally, there still exists a problem how universities coordinate publication and patent application to produce more valuable patents. Here we discussed that the patent system in Japan in this respect can be improved in several ways. Specifically, sufficient consideration should be given to the introduction of a provisional application system, expansion of the designation of societies by the Commission of Patent Office for the purpose of Art. 30 and the extension of the period for application after publication.

The “Intellectual Property Strategic Program 2009” states to “Reviewing the intellectual property system to accelerate university-launched innovation”.<sup>42</sup> We strongly hope that this statement is put into action to amend the current law to solve the above problems and to secure enough financial and human resources in universities to pursue return of university research to the public through technology transfer.

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## Notes

- <sup>1</sup> Ministry of Education, Culture, Sports, Science and Technology, “State of Industry-Academia Collaboration in Universities 2008” available at [http://www.next.go.jp/a\\_menu/shinkou/sangaku/1282374.htm](http://www.next.go.jp/a_menu/shinkou/sangaku/1282374.htm)
- <sup>2</sup> Tanaka, Saotome and Ban, “Industries’ Value Estimation of Bio-medical Patents from Japanese University”, Intellectual Property Association of Japan 7<sup>th</sup> Annual Meeting, 2009. Abstract ID3.
- <sup>3</sup> Kyoto University, “Kyoto University Outlook” p. 45.
- <sup>4</sup> Center for Innovation in Immunoregulative Technology and therapeutics (AK Project) , available at <http://www.ak.med.kyoto-u.ac.jp/index.html>
- <sup>5</sup> Tanaka and Aono, “Research on the exclusivity of pharmaceutical patents filed by Japanese National Universities”, The Journal of Science Policy and Research Management, (2008) 23(3), pp. 255-266.
- <sup>6</sup> Japan Patent Office (eds.), “Examination Guidelines” Part VII, Chapter 3
- <sup>7</sup> Tanaka and Aono, *supra* note 5, pp. 255-266
- <sup>8</sup> Saotome and Tanaka, “Management of Patent Application and Publication at University”, Intellectual Property Association of Japan 7<sup>th</sup> Annual Meeting (2009). Abstract 2J2
- <sup>9</sup> 2007 (Gyo-Ke) No. 249
- <sup>10</sup> Meaning in the test tube. Tests performed under experimental conditions (reagents, cells, temperature etc.) constructed artificially.
- <sup>11</sup> Meaning in the living body.
- <sup>12</sup> An impact factor is the calculation of the average number of citations during three years of a paper published in an academic journal. Used as an index for measuring the level of influence of that journal.
- <sup>13</sup> The research results have been submitted for publication.
- <sup>14</sup> Saotome and Tanaka, *supra* note 8.
- <sup>15</sup> Institute of Intellectual Property, “Survey report on the evaluation of intellectual property strategy for strengthening international competitiveness of Japanese industry. Survey on the Intellectual Property Statistics” (2007), pp. 81- 82.
- <sup>16</sup> Japan Patent Office, Text for seminar participants 2008, “Outline of procedures and PCT international patent application system. Recent trends in PCT international application system and framework for international applications based on the patent cooperation treaty (PCT)” (2008), with reference to a case listed on page 70, fees to attorneys was calculated as

¥200,000.

- <sup>17</sup> Support for the Acquisition of Patents – JST industry-academia collaboration and technology transfer general homepage , available at <http://www.jst.go.jp/tt/pat/index.html>
- <sup>18</sup> The number of patent application by universities in 2007 was 9,869 of which the number of foreign applications represented 2,987. See, Ministry of Education, Culture, Sports, Science and Technology, *supra* note 1.
- <sup>19</sup> Tokyo University, “Survey into industry, academia and government collaborations. Model programs related to construction of methods for industry, academia and government collaboration in the 21st century, 2007” (2008), pp. 168-169.
- <sup>20</sup> Japan Patent Office, “Regenerative medicine. Report of survey into patent application technical trends” (2009), p. 7
- <sup>21</sup> Yoshida and Saotome, “Investigation into the foreign patent applications of stem-cell technology”, Intellectual Property Association of Japan 7<sup>th</sup> Annual Meeting (2009). Abstract 2J1
- <sup>22</sup> Note that care must be taken to the data presented, since the surveyed patent applications were those of which the priority date was 2001, namely, the data were taken in the period before the universities started to make patent application seriously.
- <sup>23</sup> According to Okada, Kawahara, “Patent index and technical revolutions in the Japanese pharmaceutical industry”, the average number of countries for a patent with a priority date of 1995 covered by a major Japanese pharmaceutical company is 15 while corresponding figure for a major U.S. pharmaceutical company is 40. See, Nambu (eds.), “Studies on the Economic Performance of the Japanese Pharmaceutical Industry” (University of Tokyo Press, 2002), p. 162.
- <sup>24</sup> Tanaka and Aono, *supra* note 5, pp. 255-266
- <sup>25</sup> Saotome and Tanaka, *supra* note 8.
- <sup>26</sup> Japan Patent Office homepage, “Academic groups for the provisions of Art. 30 of the Patent Law”, available at <http://www.jpo.go.jp/cgi/line.cgi?url=/ireki/what.htm>
- <sup>27</sup> Intellectual Property Strategy Headquarters, “Intellectual Property Strategic Program 2009”, p. 31.
- <sup>28</sup> See, Saotome and Tanaka, *supra* note 8. However, the data is not shown.
- <sup>29</sup> AUTM U.S. Licensing Survey FY2005, p. 27
- <sup>30</sup> Kyoto Comparative Law Research Center, “Survey of the Actual State on Handling of Intellectual Property in Foreign Universities” (2006), pp. 38 -42; Kyoto Comparative Law Research Center, “Report of Survey of Foreign Patent Application Strategy in University International Linkages Collaboration” (2009), pp. 69-70, 79.
- <sup>31</sup> Nikkann Kogyo Shimbun, June 29, 2009.
- <sup>32</sup> Patent Law, Art. 30(1)
- <sup>33</sup> Regulations of Patent Law, Art. 19(1)
- <sup>34</sup> Regulations of Patent Law, Art. 19(2)
- <sup>35</sup> Patent Law, Art. 73(2)
- <sup>36</sup> Patent Law, Art. 73 (1)
- <sup>37</sup> Patent Law, Art. 73 (3)
- <sup>38</sup> Takada, “UNITT Management of Joint Inventions”, UNITT 2008, Fifth University Network for Intellectual Property & Technology Transfer.
- <sup>39</sup> <http://www.med.kyoto-u.ac.jp/KUMBL/office/support/mta.html>
- <sup>40</sup> Saotome, “MTA at Kyoto University” UNITT 2008, Fifth University Network for Intellectual Property & Technology Transfer.
- <sup>41</sup> Saotome and Maruoka, “Investigation into research results obtained from using a third party materials”, Intellectual Property Association of Japan 5<sup>th</sup> Annual Meeting (2007), Abstract, pp. 378-381.
- <sup>42</sup> Intellectual Property Strategy Headquarters, *supra* note 27, p. 5.