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Recent IP Trends in Regenerative Medicine

There has been great progress in medical technology in recent years, and regenerative medicine, in particular, is expected to play an important role as a core medical treatment in view of its availability and applicability. Regenerative medicine enables dysfunctional organs or tissue to recover normal function through allograft or heterograft transplantation.

This issue of IP News introduces recent IP trends in stem cell technology, which is currently attracting attention as being at the cutting edge of regenerative medicine. Also highlighted is the Japanese Patent Office's revision of the Examination Guidelines for Patents and Utility Models in order to allow for more appropriate protection of medical inventions related to regenerative medicine.

Recent Trends in Patent Applications Related to Stem Cell Technology

Stem cell technology is recognized as a promising technology in the field of regenerative medicine. Stem cells are the origin of all differentiating cells which grow into organs or tissue, and are characterized as self-renewing.

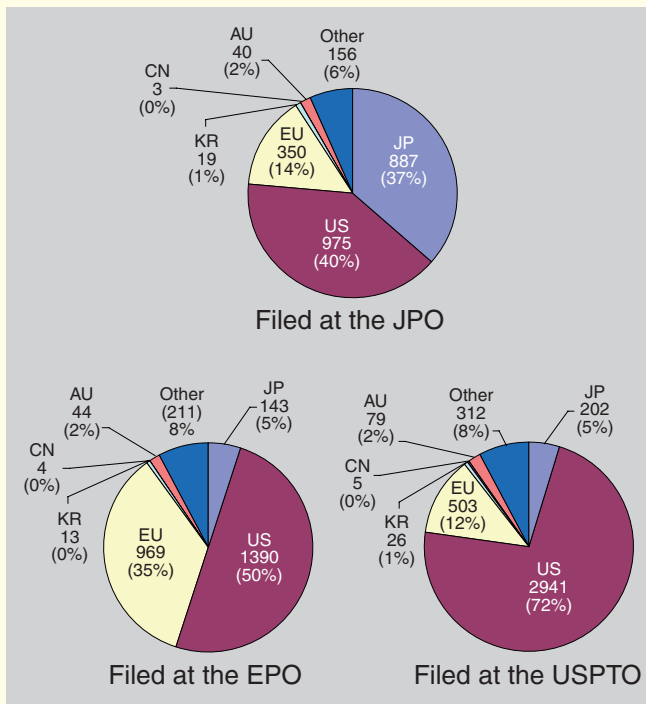
Due to these characteristics of stem cells, a wide variety of organs or tissue can be produced by differentiating the stem cells into specialized cell types.

A recent Japanese Patent Office (JPO) report illustrates how the number of patent applications related to stem cell technology has changed from 1980 to 2005 at the patent offices of Japan, the U.S., Korea, China, and Europe broken down by the nationality of the applicants. As shown in Table 1, U.S. applicants have been filing a great number of patent applications and have received patents not only from the USPTO but also from overseas patent offices. On the other hand, although Japanese applicants are second after U.S. applicants in the number of applications filed, the number of patents granted has not been correspondingly large. Moreover, Figure 1 shows that Japanese applicants are not as active as U.S. and European applicants in filing patent applications at overseas patent offices.

Table 1: Total Number of Patent Applications and Grants from 1980 to 2005

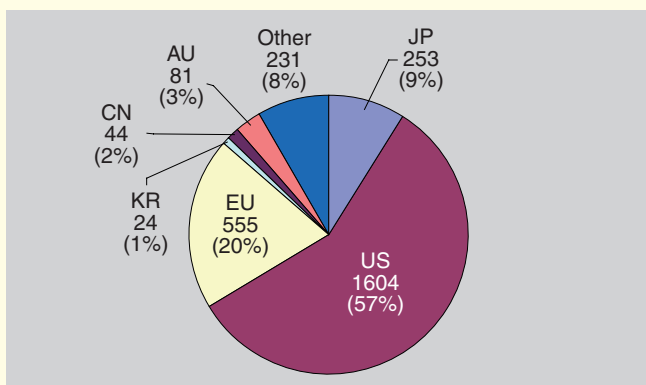
Rank	Applicant's Nationality	No. of Applications	No. of Patents Granted
1	U.S.	5,784	1,554
2	Japan	1,329	157
3	Germany	643	144
4	U.K.	355	78
5	Canada	349	100

Figure 1: Breakdown of Patent Applications Related to Stem Cell Technology Filed at the JPO, the USPTO, and the EPO



Focusing on patent applications categorized by technical field, the number of patent applications concerned with basic technology, such as differentiation and proliferation of stem cells, is the same as that for applied technology, such as regenerative medicine using stem cells. Regenerative medicine and stem cell therapy, which have attracted attention recently, account for 27% of all patent applications relating to stem cell technology. The number of patent applications in these high-profile technical fields has been increasing remarkably since 1998 and more than 50% of such patent applications have been filed by U.S. applicants (Figure 2). This illustrates the commanding lead that the U.S. has taken in research and development of regenerative medicine and stem cell therapy.

Figure 2: Breakdown of Patent Applications Related to Regenerative Medicine and Stem Cell Therapy



Patents Related to iPS Cell Technology

Research concerning stem cells has been mainly centered on the creation of embryonic stem cells (ES cells). However, since ES cells are harvested from early-stage embryos or fertilized eggs, this technique presents controversial bioethical problems. Thus, research and use of such stem cells have been restrained by governmental regulations in some countries. Alternatively, induced pluripotent stem cells (iPS cells), the efficacy of which has been demonstrated by Dr. Shinya Yamanaka of Kyoto University, are now being touted as a revolutionary alternative because early-stage embryos or fertilized eggs are not required to create iPS cells.

iPS cells are a type of pluripotent stem cell, similar to ES cells, created by artificially introducing certain genes into somatic cells. Theoretically, iPS cells are characterized by the ability to differentiate into cells of any organs or tissue of the human body.

Increasing attention has been drawn to who first filed a patent application related to iPS cells. In addition to Dr. Yamanaka’s team (Kyoto University), Bayer Schering Pharma AG also filed an application at the JPO. According to a JPO announcement released on January 22, 2009, Kyoto University filed their application before Bayer Schering Pharma AG. This JPO announcement reveals that Kyoto University may have an advantage in this brand-new technology.

Kyoto University filed an international patent application on December 6, 2006 (PCT International Publication No. WO 2007/069666), and filed a divisional application (Japanese Patent Application No. 2008-131577) based on the PCT national phase application in Japan (Japanese Patent Application No. 2007-550210). This divisional application was granted a patent (Japanese Patent No. 4183742) by the JPO on August 21, 2008. The following is the granted claim of Japanese Patent No. 4183742:

“A method for preparing an induced pluripotent stem cell from a somatic cell, comprising the step of introducing the following four kinds of genes into the somatic cell: Oct3/4, Klf4, c-Myc, and Sox2.”

On the other hand, Bayer Schering Pharma AG filed Japanese Patent Application No. 2007-159382 on June 15, 2007 (Japanese Unexamined Patent Application, First Publication No. 2008-307007) as well as PCT applications claiming priority on the Japanese patent application under the Paris Convention (PCT International Publication Nos. WO 2009/006930 and WO 2009/007852). The Japanese patent application has not yet been granted. Recently, the applicant of the Japanese patent application was changed from Bayer Schering Pharma AG to iZumi Bio, Inc., a venture bio-firm in the U.S. The Japanese patent application describes human pluripotent stem cells induced from an undifferentiated stem cell present in human postnatal tissue in which the Tert, Nanog, Oct3/4, and Sox2 genes have not undergone epigenetic inactivation.

Furthermore, it describes three methods for inducing stem cells using (1) the four genes that Dr. Yamanaka discovered, (2) three genes other than c-Myc, which is related to cancer, and (3) the three genes of (2) together with a certain compound.

The granting of a patent to Kyoto University for the method for preparing iPS cells has led to the strengthening of the support system for such burgeoning regenerative medical technology developed first in Japan. iPS Academica Japan, Inc., a newly-established IP management company entrusted by Kyoto University, manages ten patent rights concerning methods for preparing iPS cells and related technologies, and also provides nonexclusive licenses to companies and institutions working on regenerative medicine. Recently, iPS Academica has been active in concluding nonexclusive licenses with pharmaceutical companies in Japan and overseas.

Revised Examination Guidelines for Patents and Utility Models for Medical Inventions Related to Regenerative Medical Treatments

According to the JPO's provisions, "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans" are not patentable since they are not regarded as "industrially applicable inventions". Therefore, in the past, "methods which process materials (such as cells, tissue, and organs) removed from a human body under the assumption that the removed material is to be returned to the same person for therapy" had been regarded as methods for treatment of the human body, and therefore such methods which process removed materials had not been allowed. However, as technical developments in regenerative medicine continue to grow rapidly, the need for patent protection for these technologies, especially methods for processing cells, in order to promote the commercialization of medical products developed from these brand-new technologies has been recognized. Therefore, the JPO revised the Examination Guidelines for Patents and Utility Models in August 2003. The revised Guidelines describe that methods which process materials removed from the human body are now patentable. In accordance with the revised Examination Guidelines, medical inventions relating to "methods which separate or purify stem cells removed from a human body", "methods which cultivate stem cells", "methods which differentiate stem cells into tissue cells", and "methods which carry out processing before transplanting a tissue or organ removed from a human body" are now patentable. However, "methods for removal of cells from a human body" and "methods for transplantation of a processed tissue or organ into a human body" have not yet been allowed as patentable subject matter.

Japan has demonstrated a high level of technical competence in the field of basic research on regenerative medicine. However, the number of patent applications filed by Japanese applicants has remained relatively low. As described above, universities and

companies dealing with regenerative medicine in the U.S. are actively filing patent applications. To promote such breakthrough studies in Japan and to encourage the filing of applications from many industries, establishing a legal framework for IP enforcement has come to be an urgent necessity. Many feel that the enlargement of the scope of patent protection in the field of cutting-edge medical technology, such as regenerative medicine, should have already been reconsidered. Due to the tremendous impact of the successful creation of iPS cells, the JPO has finally begun reconsidering how to examine and protect inventions related to such technologies by hearing public opinions from intellectuals, some of whom insist that "methods for removal of cells from a human body" and "methods for transplantation of a processed tissue or organ into a human body" should also be patentable. The most important issue is to provide sufficient funding and personnel and to improve the legal system. A good model for patent protection of medical inventions may reside in Kyoto University's establishment of an IP management company for iPS cells. It should be expected that such IP management companies co-funded by research institutions and private companies will play an important role in developing future IP strategy.

Movements at the JPO Concerning Revisions of the Japanese Patent Law

The environment of intellectual property rights systems has been changing considerably these days across the globe due to influences from economic globalization, the rapid progress of IT, the development of open innovation for the enhancement of technology, and the expansion of M&A (mergers and acquisitions). The harmonization of intellectual property rights systems throughout the world has been developing steadily. For example, the Patent Reform Act of the USPTO is an attempt to shift from a "first-to-invent" system to a "first-to-file" system, discussions of PCT reform are underway at the World Intellectual Property Organization (WIPO), and the Patent Prosecution Highway (PPH) is being implemented among the USPTO, the UK Intellectual Property Office, the German Patent and Trade Mark Office, and the JPO, among others.

It has been 50 years since the current Japanese patent law was enacted in 1959. Even though revisions have been made, the basic tenets of the Japanese patent law have not changed since 1959. However, the JPO has begun making fundamental revisions to the law. It seems that the time has come to review the foundations of the patent system in Japan – to shift from pro-patent towards pro-innovation. The JPO's future revisions will emphasize the "promotion of the utilization of inventions", i.e., not only for the protection of inventions which is the purpose of a patent but also for the active utilization of patents.

The JPO established a “patent system study panel” (a private panel initiated by the commissioner of the JPO) comprising mainly eminent persons from the legal world, industry, and academia, as well as patent attorneys. The panel will spend one year discussing the relevant issues. In 2010, the issues will be deliberated by the Industrial Structure Council (a consulting body of the Ministry of Economy, Trade and Industry). Based on the results of this, the JPO is planning to submit a bill revising the Japanese patent law to the ordinary session of the Diet in 2011.

We will continue to update you regarding the latest revisions of the Japanese patent law in future issues of Shiga IP News. In this article, we report the issues considered by the first “patent system study panel” held on January 26, 2009.

Revision of the Effects of Patent Rights

Under the current Japanese patent law, an applicant can demand an injunction against a third party who has illegally used the patent. However, international standards are often established when several enterprises share their patents. Because the contents of patents are complicated and a single product may contain a variety of technical components, even though only one patent right concerning the product may be infringed, manufacturing or sales of the entire article may be subject to an injunction. In addition, there are patentees, such as universities, who do not conduct business. Therefore, the right to demand an injunction will be subject to certain restrictions and only the right to obtain profits will be allowed.

Promotion of Patent Utilization

To promote technological innovation, guidelines will be established for patents that are owned by enterprises or universities and opened to others, and an environment which promotes utilization of patent rights will be fostered. For example, if patentees open their patents to the public, privileges will be granted to the patentees such as a reduction in the expenses for maintaining the rights.

Expeditious and Effective Dispute Resolution

Ways of resolving disputes and procedures for trials before the JPO and courts will be reviewed.

Improvement in Quality of Patents

The examination guidelines will be clarified and revised.

Establishment of a Fast and Flexible Examination System

A flexible and expedient examination system will be provided so as to allow expedition of the granting of patents.

Promotion of International Harmonization

Establishment of a “World Patent Network” is being considered by the patent offices of ten nations: Japan, the U.S., Germany, the U.K., Korea, Australia, Denmark, Canada, Finland, and Singapore. A Plurilateral Patent Prosecution Highway (PPH) meeting attended by the heads of the offices was held in Denmark on February 20, 2009. At the meeting, there was a discussion regarding the possibility of implementing a system where information on experiences with the PPH could be exchanged. The PPH is a set of initiatives for providing accelerated patent prosecution procedures through the sharing of information between certain patent offices. It also permits each participating patent office to benefit from the work previously done by the cooperating patent office, with the goal of reducing examination workload and improving patent examination quality. The bilateral PPH has already been used between Japan and the U.K. and between Japan and the U.S., among others. The JPO is seeking international cooperation for patent examination with other patent offices, so that the burden of prosecution will be reduced and enterprises will be able to obtain patents in foreign countries more quickly. As a result, the method of prosecution in each country will be virtually unified, and it should be expected that a patent granted in the home country will be granted in other countries more easily.

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