ISSN 1880-3245
May 2012, No.31
http://www.globalcoe-waseda-law-commerce.org/rclip/e_index.html

RCLIP
NEWSLETTER
Research Center for the Legal System of Intellectual Property

Symposium of the Integrating Humanities and Science:
Research Advancement of Embryo-stem Cells and iPS Cells and the Legal Issues and the Intellectual Property Law Issues

(2012/01/21)

【Moderators】
Ryu Takabayashi, Professor of Law, Waseda University
Toru Asahi, Professor of Science and Engineering, Waseda University
【Speakers】
Makoto Asajima, Professor of Tokyo University / Fellow at the National Institute of Advanced Industrial Science and Technology
Katunori Kai, Professor of Law, Waseda University
Akihiro Umezawa, Head of Regenerative Medical Center, National Center for Child Health and Development
Shigeo Takakura, Professor of Law School, Meiji University
Masayuki Yamato, Professor of Institute of Advanced Biomedical Science and Engineering, Tokyo Women's Medical University

On January 21, 2012, the Symposium of the Integrating Humanities and Science: Research Advancement of Embryo-stem Cells and iPS Cells and the Legal Issues and the Intellectual Property Law Issues was held, hosted by Institute for Interdisciplinary Intellectual Property Study Forum ; IIPS Forum) and co-hosted by Consolidated Research Institute for Advanced Science and Medical Care, Waseda University （ASMeW）, Waseda Global COE, Research Center for the Legal System of Intellectual Property (RCLIP), and others.

This symposium invited specialists in biological science, medical science and engineering, and law, to speak on how the most advanced research of regenerative medicine using stem cells such as ES or iPS cells has developed, and what the technical issues are, and what the IP law issues are in the case of practical use.

After the opening remarks by Professor Katsuichi Uchida, Vice President of Waseda University, and Professor Waichiro Iwashi, Dean of School of Law, Waseda University, Professor Makoto Asajima gave the keynote speech on "The Current Conditions and Future Challenges in Regenerative Medical Research by Stem Cells".

Concerning important biological findings, principles have been discovered using frogs and so forth. The same system works on mice and humans. We made organs composing human body, using frogs at first, then mice, and are now attempting to make them by human materials.

In human bodies, tissue stem cells exist such as skins, hairs, small-intestinal epithelial muscles, and nerves. Researches using these cells have been done. Human embryo-stem cells (1990s) and iPS cells (induced pluripotent stem cell) (discovered by Professor Shinya Yamanaka and others in 2006) have advanced regenerative medical research significantly. It seems that regenerative medical research using stem cells

ISSN 1880-3245
May 2012, No.31
http://www.globalcoe-waseda-law-commerce.org/rclip/e_index.html

will be actively undertaken in the future. However, the research of stem cells is the midst of intensive global competition and it is prone to resultism. Detailed examination is necessary because data is a mixture of good and bad. In addition, security and certainty must be checked in a proper fashion. It is necessary to have a debate with not only a committee of expertise but also related parties in the field of cultural and social sciences. We should not conduct researches far from the law of nature and especially, we need to be extremely careful about regenerative medicine, which is related to human dignity and involved with the next generation. Furthermore, he pointed out that it was necessary to conduct researches, knowing the difference between in vitro (what is happening in the test tube) and in vivo (what affects humans), the difference between mice (pigs are sometimes used in the recent cases) and humans, and so forth.

Next, Professor Katunori Kai made a speech on “Legal and Ethical Issues Surrounding Research Advancement of ES Cells and iPS Cells”.

Professor Kai's fundamental perspective is "moderate gradual regulations". In other words, although self-regulation should be a principle, laws must get involved to a certain extent due to a limit to what a team of experts in the same position can do. The order taken in the cases as such should be the order of the soft to the hard (civil →administrative→criminal). Under such a perspective, the welfare of humankind in the future must be considered in addition to the welfare of today's humankind (people who suffer diseases now) as far as we expect influences on the future generation (the structure is similar to environmental problems with this respect).

There are numerous challenges in the ES cell research. Because it is usually associated with the loss of ES cells, the establishment and allocation guideline for human embryo stem cells stated that "human embryo and ES cells should be treated sincerely and carefully in order not to violate human dignity". There are other challenges such as infection of a donor, risks due to genetic background, risks or mix-up in selections, and canceration or teratoma formation. In addition to these, there are also unexpected risks.

The challenges in iPS cell research include a risk of teratoma formation, a risk of decreasing the effect of differentiation-induction to intended tissues, a risk of canceration triggered by the way of establishing iPS cells, and so forth. Furthermore, there are unexpected risks just like ES cells. The problem is, especially, to use iPS cells for germ cell formation (he reason why the iPS guideline was made was to deal with this problem and Article 6 of the said guideline prohibits it).

There are other issues such as informed consent, personal information protection, victim compensation (development of no-fault compensation system), and the issues in association with patent and commercialization. In amplifying on the issue of commercialization, we should not totally entrust to the private sector, however, we should not necessarily exclude the private sector. For example, it seems that biobanks should be promoted. However, in Japan, even framework is not prepared yet. If individuals establish biobanks discretely, it seems no quality assurance will be provided. Professor Kai pointed out that public and private cooperation would be best.

Then, Professor Akihiro Umezawa spoke on “The Most Recent Research of ES Cells and Its Capability”.

"National Center for Child Health and Development", at which Professor Umezawa serves as Head of Regenerative Medical Center, is a hospital for pregnant women and children. At the Center, four ES cells have been created so far. ES cells is produced by getting a fertilized embryo from hospital, cultivating it to become blastocyst, and then, cultivating inner cell mass that exist inside of the blastocyst. ES cells (inner cell mass) have two major features such as "immortal" and "can transform into any cell". As described in Professor Kai's speech, it is associated with the loss of fertilized embryo. When human ES cells were first produced in 1998, I was surprised that the way "in association with the loss of human fertilized embryo" was allowed. In the following 2010, Japan's first ES cells were produced at National Center for Child Health and Development. There is a kind of "ranking list" for stem cells. The highest rank is "fertilized embryo" which can form an individual. The next rank are "ES cells" and "iPS cells" that cannot produce individuals but are able to develop into any type of cell.

Also, when performing transplantation of ES cells, sometimes teratoma is formed. In teratoma, various organs emerge. In the comic of "Black Jack" by Osamu Tezuka, "pinoko" was made from teratoma. The idea that various things could emerge from teratoma quite surprises us. Now, the medicine intended to use these in parts is regenerative medicine.

Last, he expressed enthusiasm, mentioning the areas that the regenerative medicine using human ES cells will be applied, such as Parkinson's disease, spinal cord injury, cardiac infarction, hepatic cirrhosis, severe burn, inborn error of metabolism, hereditary skin disorder, and others.

After the break, Professor Shigeo Takakura presented on the theme of "Patent System and Bioethics". Article 32 of the Patent Act stipulates that "any invention that is liable to injure public order, morality or public health shall not be patented". You may think examines judge public order and morals in examination, but in fact, that is not the case. Considering Professor Takakura's experience when he was an examiner, he said he had never been conscious of Article 32. However, there are decisions related to ES cells in the recent cases. So-called the University of Edinburgh patent【1994－522943】was rejected in examination (however, a patent was later granted to only non-human embryos). In contrast, JST patent【2001－99074】was granted. This difference seems to reflect the difference that the claim itself includes the process of "destroy embryos". But they do not differ with respect to using fertilized human eggs.

In Europe, Article 53(a) of European Patent Convention (EPC) has clauses corresponding to Article 32 of Japan's Patent Act. In addition, Rule 28 of the Implementing Regulations stipulates that patents shall not be granted to human embryos (in addition to the EU member states, 11 states including Switzerland and Liechtenstein participated in the EPC). Concerning these EPC provisions, there is a case relating to the University of Wisconsin patent In this case, Enlarged Board of Appeal at the European Patent Office (EPO) decided that although the claim itself did not include the process of "destroy embryos", it conflicted with Article 53(a) EPC as far as it used "the human embryos broken by someone somewhere" However, probably considering there is little room for granting a patent on inventions derived from human embryos, the EPO later streamlined their practice as the following. In other words, after May 9, 2003, human ES cells become available to the public at a part of trusted international organizations (ES cells are available without destroying human embryos). Therefore, as to the inventions with the application filing date after May 9, 2003, the EPO said exploitation of inventions would be possible without destroying human embryos. On the other hand, Brustle case (the validity of patent related to ES cells granted in Germany became an issue at German Federal Patent Court. Since it was an issue for the whole EU, a preliminary decision was asked for

European Court of Justice.） The issue was about Article 6(c) of EU bio Directive (it is the same article as Rule 28 of EPC regulations, but applied to only EU member states). The ECJ made a decision that patents shall not be granted regardless of date of destroy or claim when it is accompanied with destroy “human embryos”.

In the U.S., there is no provision for public order and morals under the Patent Act. Therefore, it can be said that, as far as looking at the wordings of laws, examiners in the U.S. do not make decisions on public order and morals. In the background, there exists an idea that the judgment on public order and morals should be made not by examiners but by the legislation of the Parliament.

In summary, as to the examiner’s judgment on public order and morals, the U.S. does not look anything, EU look closely, and Japan is between them. When patents are not granted due to its violation of public order and morals, the invention is available to everyone. It is controversial whether it has any meaning in that case. As a national government, it has just a negative meaning such as putting out a message that they do not encourage the relevant invention. Probably, we do not need to find significant meaning. The speaker concluded that, in such circumstances, the role expected of examiners at patent office would be to judge whether the relevant invention has damage on human or not, in light of the technical level.

Last, Professor Masayuki Yamato spoke on “The Current Conditions and Challenges in iPS Cells".

There are numerous diseases that cannot be cured by traditional treatments or medicines. When certified as an “incurable disease”, medical expense will be covered by the national government. However, it is still not cured by the traditional treatment and things do not progress. In such circumstance, expectations are placed on regenerative medicine.

Regenerative medicine can be divided into four categories. The first is the category replacing the lost stem cells (for example, bone-marrow transplantation to a patient with broken bone marrow or corneal treatment). The second is the category stimulating wound healing/tissue repair (for example, skin maintenance). It is enough to have stimulation; therefore, it does not need to be the patient’s cell. It can also work on others' cells. The problem is how to obtain others’ cells. In the U.S., circumcision is practiced as religious custom and a lot of foreskins were produced at circumcision. Although a mechanism is unknown, private companies obtain them to sell in the market. Currently, the research to stimulate wound healing/tissue repair using iPS cells is also conducted. The third is prosthesis of lost tissues (for example, a collage or hyaluronic acid shot for laugh lines). The fourth is modulation of inflammation/immune response (for example, implant other’s mesenchymal stem cell to a child who had bone-marrow transplantation and suffers skin sore).

Expectations to ES cells and iPS cells include the following points. Somatic stem cells have limited proliferating ability but ES cells and iPS cells have ability to proliferate indefinitely. In addition, for somatic stem cells, it is difficult to create cell banks free from immune rejection. However, it seems to be possible for ES cells and iPS cells. Because ES cells and iPS cells are artificial cells, those cells would be easier to be marketed on a commercial basis or applied to intellectual property than somatic stem cells. Currently, research teams provide oral mucosa and so forth each other for research. It is permitted because it is done within universities. If the same thing is practiced in companies, it might raise a legal problem. Therefore, the speaker concluded that it should be necessary to have examination on some kind of legislation.

After the speeches stated above, a panel discussion took place under the moderation of Professor Asahi and Research Professor Yasue Fukuda at Osaka University School of Medicine.

ISSN 1880-3245
May 2012, No.31
http://www.globalcoe-waseda-law-commerce.org/rclip/e_index.html

For example, concerning the issue of patents derived from human embryos, it is understandable that it relates to the issue of bioethics. However even abortion is sometimes permitted in Europe. While abortion is allowed, why is it prohibited to destroy human embryo? First of all, disposing human embryos is not regulated. Why so? Those questions were raised. In response, Professor Takakura made a comment: There might be a sense of value that disposing human embryos is inevitable but using them as a some sort of device is unacceptable. In addition to these, various discussions were made and the seminar successfully ended.

(RC Shun Kuwabara／RA Asuka Gomi)

ISSN 1880-3245
May 2012, No.31
http://www.globalcoe-waseda-law-commerce.org/rclip/e_index.html

RCLIP

RCLIP Workshop Series No.33

(2012/03/05)

【Moderator】

Toshiko Takenaka, Professor of University of Washington

【Speakers】

Christoph Rademacher, Assistant Professor of Waseda University, Attorney-at-Law (New York)

On March 5, 2012, a seminar on injunctive relief in US patent litigation was held at Waseda University, focusing on the different standards at US District Courts and at the International Trade Commission.

After a brief introduction of Professor Takenaka, the speaker of the seminar, Christoph Rademacher, explained the background of the revised standard for claims for injunctive relief pursuant to the so-called *eBay*-test issued by the US Supreme Court in 2006, requiring the patentee to show, amongst others, irreparable harm in case the court would not grant an injunction. One objective of the Supreme Court was to make it more difficult for Non-Practicing Entities (NPEs) to obtain an injunction order. The speaker examined the effect of the eBay test, and presented some statistics on injunction grant rate by type of patentee.

The main focus of the presentation of Prof. Rademacher was on patent enforcement at the International Trade Commission (ITC). First, he introduced basic features of the ITC and introduced major procedural differences between US District Courts and the ITC. Firstly, the ITC can only get involved when examining patent infringement by importation. If the infringement occurs purely within the US, the ITC doesn't have jurisdiction. However, due to the increase in cross-border trade especially in the area of electronics products, the ITC became a much more important and popular forum for patent litigation in the US over the last ten years. Also, the ITC can only award injunctive relief by issuing exclusion orders, but has, unlike District Courts, no authority to award damages.

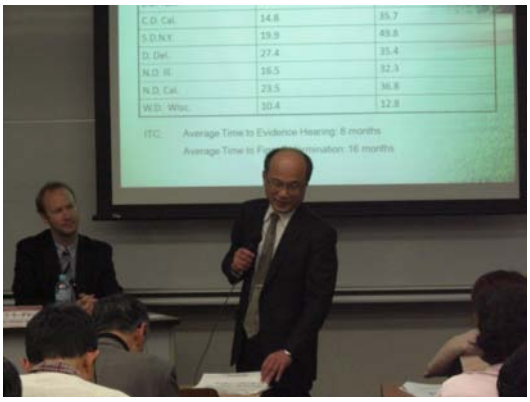
Another substantial difference examined in the presentation is that a complainant at the ITC has to show that it maintains a domestic industry in the US. Prof. Rademacher introduced the test applied to examine the domestic industry requirement, and explained that under recent case law also NPEs can often satisfy the domestic industry requirement by demonstrating an established licensing program.

Prof. Rademacher furthermore analyzed whether the ITC should use a test similar to the *eBay*-test before issuing exclusion orders. Recent case law confirms that the eBay-test is not directly applicable to the ITC, as the procedural law applied by the ITC derives from a different statute. Exclusion orders at the ITC are, however, subject to the requirement that they don't violate public interest. Prof. Rademacher analyzed the three existing cases in which the ITC refused to grant an exclusion order due to public interest considerations, the last of which was decided in 1984. Since then, the ITC has never refused to grant an exclusion order due to public interest considerations. Prof. Rademacher concluded his presentation by holding that while it is unlikely that the ITC will start applying the eBay test anytime soon, public interest concerns may at least result in generous grace periods before the infringing product has to be removed from the market, allowing the infringer the design-around the infringed patent if the infringement is only of minor nature.

ISSN 1880-3245
May 2012, No.31
http://www.globalcoe-waseda-law-commerce.org/rclip/e_index.html

After the Prof. Rademacher's presentation, Prof. Takenaka noted that due to the background of the ITC, the equity test applied by District Courts under eBay is different from the public interest at the ITC. In the Q&A session, questions were raised by the audience as to the criteria applied for dividing NPE's when analyzing eBay, and as to the key to the ITC's quick resolution process.

The seminar was attended by many participants, and was very successful.



(Christoph Rademacher, Assistant Professor of Waseda Institute for Advanced Study)

The IP Precedents Database Project

IP Database Project: China

We publish 100 Chinese precedents of six regions in China. We will advance the project further as planned with the collaboration of Chinese Professors and collect 120 cases.

(Global COE Researcher Yu Fenglei)

IP Database Project: Korea

In addition to the current 141 precedents at the database, we are negotiating with Korean collaborators to add more precedents in the FY 2012. Also, a visit to Korea is also planned to renew the agreement with the collaborators.

(RC Lea Chang)

IP Database Project: Thailand

Currently 462 Thai precedents have already been placed at the database. 21 cases collected in FY 2011 will be added soon.

(RC Tetsuya Imamura)

IP Database Project: Indonesia

We are planning to discuss the plan for 2012 with Attorney Fiona Butar-Butar in the near future.

(Research Associate Noriyuki Shiga)

IP Database Project: Taiwan

40 cases were added to the DB in FY 2011. So far 575 precedents in total were published. As for this fiscal year, we plan to add more precedents, having collaborative relations with the working group in Taiwan.

(Research Associate Akiko Ogawa)

IP Database Project: Europe

As the DB pproject of last year, we obtained the 50 German cases, 85 French cases, 50 Spanish cases, 30 UK cases. Those will be placed at the DB. We are discussing with collaborators to further collection for this fiscal year.

(RCLIP Office Staff Chiemi Kamijo)

ISSN 1880-3245
May 2012, No.31
http://www.globalcoe-waseda-law-commerce.org/rclip/e_index.html

Events and Seminars

Global Patent Strategy Conference

【Date】June 30, 2012 13:30~18:10

【Place】Waseda University, Ono Memorial Hall

<Part I>

Keynote Speech: Mark Lemley, Stanford Law School

"U.S. Patent Litigation based on Empirical Data"

【Panel Discussion】

Pre-Filing Issues (Warning letter, evidence taking, forum shopping etc.)

【Moderator】

Christoph Rademacher, Assistant Professor of Waseda Institute for Advanced Study

【Panelists】

Paul Meiklejohn, Partner, Dorsey & Whitney, Seattle, USA

Tilman Müller-Stoy, Partner, Bardehle Pagenberg, Munich, Germany

Felix Einsel, Partner, Sonderhoff & Einsel, Tokyo

Mark Lemley, Professor of Law, Stanford Law School

<Part II>

【Speech】

Yoshihiro Endo, Intellectual Property Dept. at Honda Motor Co., Ltd.

"Global Patent Strategy Trends in Japanese Industry"

【Panel Discussion】

Challenging Validity (Opposition, Reexam and Invalidation Procedures and Their Impact on Patent Procurement and Infringement Procedure)

【Moderator】Toshiko Takenaka, Professor of University of Washington School of Law

【Panelists】

Jan Krauss, Partner, Boehmert & Boehmert, Munich, Germany

Christof Karl, Partner, Bardehle Pagenberg, Munich, Germany

Douglas F. Stewart, Partner, Dorsey & Whitney, Seatle, USA

Hiroyuki Hagiwara, Partner, Ropes & Gray, Tokyo Yoshihiro Endo

【Host】

Institute for Interdisciplinary Intellectual Property Study Forum ; IIPS Forum）

【Co-host】

Industry Alliances Division, Tokyo Medical and Dental University

Waseda Global COE, Research Center for the Legal System of Intellectual Property (RCLIP)

Editor/issuer
Ryu Takabayashi,
Director of Research Center for the Legal System of Intellectual Property (RCLIP)
Waseda Global COE Program
Web-RCLIP@list.waseda.jp
http://www.globalcoe-waseda-law-commerce.org/rclip/e_index.html