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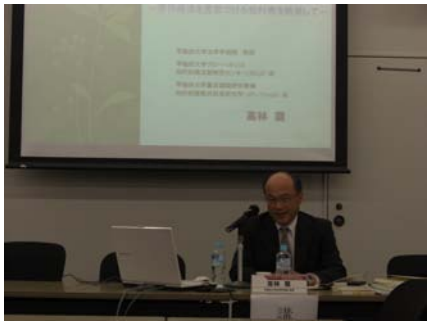
NEWSLETTER
Research Center for the Legal System of Intellectual Property

RCLIP Workshop Series No.32
Copyright Hermeneutics - Writing a Text Encouraging Copyright Law - (2011/5/16)
Speaker: Ryu Takabayashi, Professor of Law, Waseda University



At the RCLIP Workshop Series No.32 on May 16, RCLIP Director Ryu Takabayashi, who has taken the rostrum of the recent RCLIP workshops and seminars only as a moderator for a while, appeared as a speaker this time and presented on the issues surrounding copyright hermeneutics that he came up with while writing "Copyright Law From the Ground Up" (YUHIKAKU Publishing) published in December 2010.

This report first pointed out the differences of the backdrop between the year of 2010 and the year of 2002 when he published "Patent Law From the Ground Up". 2002 was the year when right protection was exclusively enhanced while 2010 was the year when harmonization was focused between IP protection and promotion of utilization. Then, the report presented the following arguments, starting with the difference in structure as IP Law between patent Law and copyright Law.

First, since copyright law consists of bundle of rights, while patent law adopts a firm structure of real right, it is difficult to measure usage of the right in terms of the effect in transfer or grant of a right, or maintenance of the perfection. In addition, the contents of rights are expressed in the words such as the scope of patent claim in the case of patent law which considers registration after examination as the requirements for granting rights. On the other hand, in the case of copyright law which adopts no principle scheme, the plaintiff who brings an action to the court, alleging infringement, must attest to "a production in which thoughts or sentiments are expressed in a creative way", which is a requirement for granting rights, as a cause of claim. When taking up the requirements for creativity each by each, tough tasks are always required such as search for the creative part which is newly added to the original work, in the present circumstances where many works are created based on other works, for example, secondary work, tertiary work, and so forth.

Next, he pointed out the issue in the case of copyright which is a relative exclusive right. For example, in the case of reproduction right infringement, subjective requirement such as "reliance" is necessary. The issue here is whether we should consider the unintended acts as those equipped with subjective requirement, for example, the act of pushing a button to start an automatic copying machine or "unintended appearance" which is recently taken in the copyright law reform. Then, he expounded on the issue of whether to require the same level of subjective intention as "reproduction" for different bundle of rights like "public transmission", by citing the cases which was respectively ruled by the Supreme Court in January: "MANEKI TV" (judgment of the third petty bench of the Supreme Court on January 18, 2011, Hanrei Jihou 2103, p.124) and "ROKURAKU-II" (judgment of the first petty bench of the Supreme Court on January 20, 2011, Hanrei Jihou 2103, p.128). In the case of

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"ROKURAKU-II", as the act of reproduction, the decision ignored the meaning of the user's act of setting the machine to specify the program to be recorded. As the critical part of copying act, the Court recognized the provider's act of deciding the frame of copying objects and pumping copying objects into it. It concluded the act was the act of reproduction itself. On the other hand, in the case of "MANEKI TV", concerning the act of inputting TV programs into a device considered to be an automatic public transmission apparatus so as to transmit them to users, the Court did not recognize the act of placing copyrighted works at an automatic public transmission apparatus as the act of making transmittable but recognized that act as the act of making transmittable based on the fact that the act "created a situation" to transmit the programs at the request of users. According to his analysis, in other words, concerning the reproduction which must require concrete acts such as making reproduction based on a copyrighted work by an actor himself, the decision incorporated the acts such as setting the framework of copying objects or conducting the critical act for user reproduction by transforming the acts into the act of reproduction itself. On the other hand, concerning the act such as the act of transmission which could be considered colorless, the decision tried to make a balance by requiring subjective acts such as "creating a situation" in order to prevent the scope to spread and include so-called cloud providers or service providers.

Last, he discussed the relations between the absolute concept of property rights in France and the concept of "restrictions on rights" in restrictive regulations of copyright and moral right. The concept of absoluteness of rights is based on the understanding that property rights are recognized as social and public existence essentially. He pointed out that, because of that, it would be possible to choose a way to permit parody without restricting copyright.

In conclusion, he emphasized that it was necessary to interpret the law by benefit balancing and value assessment based on the perspective of the justice of law in interpreting the copyright law as is the case in the interpretation of other general laws.

Following the stated above, a QA session took place and the workshop ended successfully.

(RCLIP Director Ryu Takabayashi)

＜The Third IIIPS-Forum IP Symposium of the Integrating Humanities and Science＞

Symposium: IP and Global Health Strategies
Development of Legal Framework for Japan's Leadership in Global Community

(2011/6/4)

【Opening Remarks】

Satoshi Shimizu, Vice President of Waseda University

【Moderators】

Toru Asahi, Professor of Faculty of Science and Engineering, Waseda University

Toshiko Takenaka, Professor of School of Law, University of Washington; Director of CASRIP

【Speakers】

Keizo Takemi, Professor of School of Political Science and Economics, Tokai University

Ryu Takabayashi, Professor of Law, Waseda University

Masanobu Katoh, President of Intellectual Ventures Japan

Hidero Niioka, Managing Director, CEO, IPALPHA

Dan Laster, General Director, PATH; Part-time Lecturer of UW School of Law

Yasushi Katsuma, Professor, Faculty of International Research and Education; Director of Waseda Institute for Global Health, Waseda University

【Closing Remarks】 Kaori Iida, Associate Professor; Director of Industry Alliance Division, Tokyo Medical and Dental University

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The third symposium was held on June 4, organized by Institute for Interdisciplinary Intellectual Property Study Forum: IIPS Forum. It started with the opening remarks by Professor Satoshi Shimizu, Vice President of Waseda University. Following the second symposium in last February, under collaboration between law and medicine, this symposium invited researchers and legal professionals of global health profit/non-profit organizations from Japan and the US as speakers to discuss new development of legislative infrastructure for IP exploitation.

First, Professor Keizo Takemi, School of Political Science and Economics, Tokai University, made a keynote speech titled "Power Politics and Global Health in the 21st Century". Professor Takemi first pointed out that, although the study field of "public health" was an important part in policy studies, this filed was positioned narrowly in medical school in the case of Japan and therefore, the development of this field had been rather impaired. He explained that, while advocating medicine or medical care, the role of "public health" must be to reliably develop policy studies responding to various actual problems by mobilizing social science related to medicine or medical care.

Next, based on his experience of establishing his own expertise by integrating international politics and healthcare, Professor Takemi stated that, in the 21st century when transnational common issues were emerging one after another, the strengthening of power politics to integrate diplomatic power and the specialized field that had a comparative advantage domestically would become an major task for Japan in order to resolve these common issues. He insisted that, in discussing transnational common issues such as "global health", it was essential to create transnational network of public-public or public-private cooperation, and to have a policy concept based on universal values which could be backed by the understanding and support of different countries or private organs such as individual NGOs when implementing the resolution. In that sense, in the trend of global health including the aging global population, the changes in disease structure, the approach to strengthen health system, and the symbolization of "Universal Coverage"[1], it was revealed that Japan had a comparative advantage in the field of healthcare from the fact that Japanese average life expectancy and healthy life expectancy had been increased and 50 years had passed since the adoption of a public healthcare insurance system. Professor Takemi insisted that Japan should make use of this high comparative advantage.

Last, he raised five issues to be solved in the future in order to make use of Japan's comparative advantage at the end of his speech: the establishment of political leadership with intellectual conception ability, fostering as well as facilitating the use of human resources for global health policy, information sharing and creation of network function beyond vertically divided administration, and the establishment of close cooperative relationship between administration and private sector (companies and NGOs)

In the session 1, first, Professor Ryu Takabayashi, Waseda University spoke on various discussions held in the previous symposium[2], with the title of

[1] defined "as securing access for all to appropriate promotive, preventive, curative and rehabilitative services at an affordable cost (WHA58.33, 2005)"

[2] The 2nd symposium can be viewed at the following site. http://www.globalcoe-waseda-law-commerce.org/rclip/20110226/

"Patents in Life Science: Barrier to Vehicle for Promoting Open Innovations-Review of Current Japanese Legal Frameworks". Next, Mr. Masanobu Katoh, President of Intellectual Ventures Japan, spoke on "Introduction of Intellectual Ventures' Business Model and Examples of Activities in Global Healthcare".

In addition to the problems such as complexity and sophistication of technology as well as huge cost of R&D, the development of today's medical and pharmaceutical supplies has increasing risks and burdens of developing technology alone. Furthermore, emerging companies having little own research organization come out and there is a tendency of separation between R&D and marketing. He stated that it would be necessary to have open innovation among companies, research institutions, and universities, with such various requirements. Under the circumstance as such, Japanese R&D tends to be no good at uniting technology and society (market) and lacks "market driven" technology development to make the future market vision a reality. In addition, in the so-called "lost 20 years" or economic crisis, companies have shifted their R&D to the ones which directly connect business and as a result, led to difficulty with conducting mid-and-long term "innovative" technology development. Moreover, Mr. Katoh pointed out that it was difficult for Japanese companies to have an explosive hit in the global market because the so-called "independent technology" was the mainstream idea in Japanese companies.

In order to change these conditions of Japanese R&D and lead global business, in addition to excellent technology, it is necessary to have the ability to develop and realize new business model and the ability to judging technology with business sense, as well as global knowledge and analyzing ability on technology and market. It is also necessary to have not only research of natural science but also elements of social science approach such as sociology, psychology, management, and law, and a continuous scheme to refine and modify (sometimes abandon) R&D with the consideration on market or output. Mr. Katoh analyzed that these were important elements to connect technology with innovation (constituent elements of innovation ecosystem) and there would be limitations to seek a resolution only to researchers. Therefore, he stated that it was important to develop "innovation ecosystem". It is a scheme of providing managers and engineers with comprehensive services by the collaborative network among consultants (researchers who have abundant business experience and can assess and coordinate technologies with a wide perspective), professionals (accountants or lawyers who understand not only own area of expertise but also technology or business), investors (venture capitals, investment partner, other financial experts who has knowledge of technology and business), and producers (business professionals who know technologies and can manage business).

According to Mr. Katoh, there is a huge difference between Japan and the U.S. in this respect. In the U.S., the external environment has been already developed in order to nurture venture enterprises over time. The ecosystem has been developed by venture capitals, accountants or lawyers who understand technology or business, experts in finance or marketing, and consultants who can assess technology. On the other hand, in Japan, when trying to realize open innovation, there are a limited number of specialists such as

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lawyers around and the ecosystem is imperfect. Japanese accountants and lawyers only counsel on their own expertise (in comparison to internal experts within major companies) and there are less independent external experts such as technical consultant.

At the end of the speech, he introduced his company: Intellectual Ventures' business model and their activities in the field of global health as an example. In their practice, they introduce Japanese excellent technology to the world and provide Japanese researchers with more opportunities as well as introduce foreign unknown technologies in Japan and support open innovation in Japanese companies. Referring to these practices, Mr. Katoh showed the future vision of Japanese innovation ecosystem.

At the end of the session 1, Mr. Hidero Niioka, Managing Director, CEO, IPALPHA, spoke on "Current trends of Pharma business, finance and IP strategies: Emerging markets and Japan". It covered five problems: "Current Pharma Market", "Emerging Market", "Generics Market", "Japan", and "How to foster more IP Innovation".

First, showing IMS Health's data and prospect on the global pharma market from 2009 to 2015, Mr. Niioka stated that the one driving the future market growth would be the emerging markets like China. The past rule: "Patents + MA (Marketing Authorization) = Pharma Co's Revenues" is not the case today. In the trend as such, it is necessary to reaffirm the significance of generic market in emerging countries. Various issues can be thought to be the cause of such conditions: the end of the era of blockbuster new drugs, the advent of patent cliffs, the limitation of cost-cutting, pricing pressure, less R&D budget, and less funds granted to public institution for fostering innovation. Considering the remarkable growth of generic markets in emerging countries, various countries in the world are saving costs by switching from originator to generics. It is also one of major factors and in fact, to acquire MA in emerging countries is less expensive and in a shorter time. However, enforcement of IP rights remains a problem to develop generic business in some emerging countries. Therefore, as the IP strategy for patent holding companies, they must still file patents in those countries. In addition, according to Mr. Niioka's analysis, it is important to bring in domestic people with strong network and sourcing capacity, considering measures such as building companies, joint venture, M&A, and strategic alliance in the emerging markets.

What is the condition in Japan, the 2nd largest pharma market globally? As Japanese population is rapidly aging, healthcare cost is increasing, causing pressure on national finance. Under such a condition, Japanese pharma companies are facing the aforementioned issues such as patent cliffs and so forth. Especially, we can see the tendency that long MA processes make JP original innovation go abroad. Mr. Niioka insisted that it was necessary to globalize Japanese pharma market by taking measures such as increasing governmental support for generics market, developing more M&A or even new businesses in Japan, giving incentives for foreign companies to come in and foster R&D in Japan, and making Japanese pharma companies reach out to emerging markets.

However, even so, new drugs development should not be abandoned. In the case of Japan, the issue was raised about how public and private funds support R&D to improve international competitiveness in new drug development and healthcare sector. How do we get more innovative products in the healthcare sector from Japan? How can we market these Japanese innovations abroad? How does an open innovation system help? We need to study these concrete issues. Last, Mr. Niioka proposed concrete measures including strengthening R&D quality and efficiency, catching the international trends, improving process of marketing approval, having stronger international sales & marketing forces and stronger remuneration incentives,

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financial aid to academic institutions (venture fund or venture capital), establishing university participating investment structure (joint venture or strategic alliance), deregulation on patent drug research by institutions such as universities or competitive companies, and adopting financial support or remuneration system to university researchers (for example, OLT at Stanford University). (RA Po-Chun Chen)

Next, under the moderation of Professor Toshiko Takenaka, University of Washington; Visiting Professor of Waseda University, session 2 started with the theme of "What to Learn from U.S. Experiences: Non Profit IP Strategies for Global Health: Partnerships with Pharmaceutical and Biotech Firms".

First, Mr. Dan Laster, General Director, PATH; Part-time Lecturer of UW School of Law presented on the theme of "Product Development Partnerships to Further Global Health in Developing Countries: IP and Data Access Issues". After introducing NGO PATH, he explained about the issues including evolving global health architecture, role of product development partnerships, intellectual property, and data access.

According to the global map showing deaths from infectious and parasitic diseases, the number in Africa is extremely high and the number in advanced countries is very low. Benefits of funding and participation in global health arena include humanitarian and diplomatic benefits as well as technology development and access and market development. In addition to country funders such as US, UK, and Norway, multinational institutions such as Unicef, WHO, and EU, and foundations such as Rockefeller Foundation or Bill and Melinda Gates Foundation, he introduced new frameworks such as Global Alliance for Vaccines and Immunization(GAVI) and policy tools including U.S. FDA Priority Vouchers as new architecture of global health.

Then, Professor Yasushi Katsuma, Faculty of International Research and Education; Director of Waseda Institute for Global Health, Waseda University, presented on "Public-Private Partnerships for Global Health".

From the perspective of Corporate Social Responsibility (CSR) with emphasis on "Do No Harm", as the keyword of PPP (Public-Private Partnership), Professor Katsuma introduced the following with concrete examples. 1) Financial contributions to UN agencies and NGOs through CSR alliance, 2) Technical assistance, 3) Private sector advocacy such as World Economic Forum, 4) Health education within business and for the clients, 5) Participation in UN procurement business, 6) Innovative mechanism for fund procurement, and 7) Technological innovation to enhance global public goods.

After the speech, a panel discussion took place with the speakers of the session 1 and 2.

After the QA session, Associate Professor Kaori Iida, Director of Industry Alliance Division, Tokyo Medical and Dental University addressed closing remarks and the symposium, which started at 13:00, ended at 18:00.

(RC Lea Chang)

Symposium: The Origin, Current Practice, and Future Vision of Bayh-Dole System - The Significance and Scope of Patent Protection on Upstream Inventions (2011/06/21)

【Moderator】

Toshiko Takenaka, Professor of School of Law, University of Washington; Director of CASRIP

【Speakers】

Edmund Kitch, Professor of Law, University of Virginia School of Law

Andrew Serafini, Partner, Fenwick & West

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【Panelists】
Sadao Nagaoka, Professor of Hitotsubashi University
Ichiro Nakayama, Professor of Kokugakuin University

This symposium was held on June 21, 2011, organized by Technology Licensing Organization, Tokyo Medical and Dental University and co-organized by Research Center for the Legal Systems of Intellectual Property (RCLIP), Waseda Global COE, and the Center for Advanced Research and Study on Intellectual Property (CASRIP), University of Washington.

1. Keynote Speech

Professor Kitch made a keynote speech titled "Prospect Theory and the Bayh-Dole System".

He explained the prospect theory, the connection between the theory and the Bayh-Dole act, and the recent development in the U.S. as the following.

According to previous economic theory, while the patent creates the incentive for the investment, it creates monopoly, resulting in a trade off. However, the explanation as such is incomplete. The existence of the patent rights creates incentives for future investment in efforts to increase the value of the exclusive rights. It also lowers the cost of the coordination necessary for an efficient search for that purpose. For example, in the mineral claims system, the exclusive ownership is conferred on the claim owner before the investments necessary to open and operate the mine have been made (at the point of prospects), rather than after the mind ore is in hand. These ideas become known as the prospect theory. In his article written in 1977, Professor Kitch stated that the prospect function suggested the granting of exclusive licenses of patents on inventions resulting from federal grants, in need of further investment. However, it is not certain whether the prospect theory introduced in 1977 provided direct influence on the provisions of the Bayh-Dole act in 1980. Professor Kitch still thinks that the basic idea behind Bayh-Dole makes good sense in terms of decentralizing the ownership instead of managing inventions by federal bureaucracy.

To introduce the recent developments in the US, he introduced the report published by the National Academy of Sciences (NAS) in 2010 on management of university intellectual property. Especially in this report, a proposal for "free agency" was explained.

A proposal for "free agency" decentralizes the right ownership from universities to faculty so that faculty can be given the right to own their inventions, just as the Bayh-Dole act decentralized the right ownership from the bureaucratic centralized government to universities against a backdrop of TLO's insufficiency. However, in the NAS report, this proposal was not adopted. Next, as the U.S. Supreme Court decision related to Bayh-Dole, the cease of Stanford v. Roche 563 U.S. __ (2011) was introduced. The Supreme Court ruled that the Bayh-Dole act did not acknowledge transfer of faculty's right regardless of the existence of contractual agreement although the act set up the ownership of rights belong to universities.

2. Speech

Attorney Serafini made a presentation with the theme of "Technology Transfer Practice Today: Scope of Upstream Inventions".

Concerning the subject invention in basic research of the Bayh-Dole act, the issues of enablement, written description, and patentabe subject matter become a problem. Among them, written description requirement exists separate from enablement requirement. The CAFC en banc decision on Ariad v. Eli Lilly, 598 F. 3d 1336 (Fed. Cir. 2010) also reaffirmed that fact in the ruling. It is important to see whether the inventor is in "possession" of the invention in light with specification. Also, as to patentable subject matter, Bilski USSC decision (Bilski v.

Kappo, 561 U.S. 2010) ruled that machine or transformation test was not an exclusive test and patentable subject matter is judged by determining whether the subject falls under three exceptions such as laws of nature, physical phenomena, and abstract ideas. However, one of later decisions ruled that administering and determining steps were "transformative" (Prometheus v. Mayo, 628 F. 3d 1347(Fed. Cir. 2010), the Supreme Court granted certiorari against the decision). As suggestion from case law, the necessity of strategic patent filings for upstream inventions could be raised. It is necessary to understand the difference between a discovery and an invention. Additional experiments are necessary to fully describe the invention even though those experiments are less interesting to an academic researcher. In addition, to avoid spending resources writing useless applications, it is beneficial to use patent committee to review discoveries to analyze which discoveries lend themselves to inventions for patent applications.

3. Panel Discussion

First, Professor Sadao Nagaoka made the following comments.

In the past, economists used to believe that an innovation is naturally developed. However, now they have better understanding of the complexity of innovation process and the role of the patent right. Among some advocated models, the theory that Professor Kitch pointed out is theoretically very complex. That is the issue that patentees coordinate complementary R&Ds necessary to put into practice efficiently germinating inventions, by licensing. Currently, many economists are studying this issue, trying to discover the significance of Professor Kitch's theory. On the other hand, different from mining rights, the scope of patent rights as the prospect may not be well defined. He said that he would like to question that point. The tendency that recent precedents strictly apply written description might be related, but the weak notice function is pointed out by Bessen and Meurer. Especially, because (part of) claims are added through continuation practices, the prospect is not defined beforehand but might be expanding ex post. This point might be the important issue.

Next, Nakayama made the following comment.

Traditional incentives focus on the ex ante incentives for creation and consider patent as exclusive right which limits use of inventions. In contrast, the prospect theory focuses on the ex post incentives for future investments and consider patent as property right which promotes businesses. Although theoretical contribution of the prospect theory is significant, it is controversial for that reason. However, the traditional incentive theory does not explain well the meanings of university's acquiring patents. The prospect theory seems to provide better explanation such as triggering investments for putting into practice of inventions. The prospect theory is considered as a theoretical pillar of the Bayh-Dole. On the other hand, the challenges could be raised as the following issues: whether the all university inventions need additional investment as the prospect theory assumes so; whether the university TLO could be considered as capable in managing inventions, as questioned in the recent discussion on free agency; whether the right to receive a patent is belong to universities, as the US SC decision made clear; what influence the recent precedents have the prospect function; what is the significance of university's filing a patent lawsuit as patentee.

Professor Kitch responded to these comments as the following. The prospect theory is not normative. He did not mean that wider claim is better and, in fact, it is difficult to determine the extent of claim. The decisions of precedents are made for individual cases in principle. With regard to the purpose of IP activities by universities, many TLOs are in severe financial conditions and university management pressure them to earn a great deal of money by big hit

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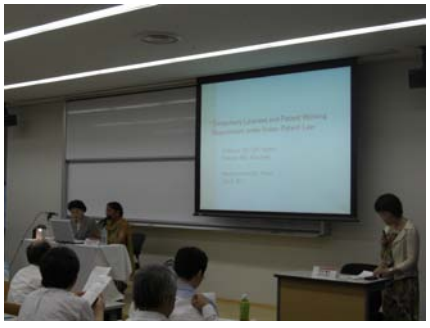
innovation. The NAS Report, however, opposes such an approach. The main purpose of IP activities by universities is not to generate profit but to pass on technology to the society.

Then, a discussion was made concerning university's filing a patent lawsuit. There is a budgetary restriction when universities actually file a lawsuit. In some cases, licensees put pressure. While licensees pay royalty, competing infringer does not pay it. In that case, obviously licensees can ask uiversities who are patentees to exercise the right. On the other hand, universities who are patentees have to file a lawsuit if the duty to exclude infringement is included in an exclusive license contract. If not, the existence of infringer means that the infringer could put into practice invention without having patent incentive for additional investment. Therefore, it could be said that obtaining patent was not necessary from the beginning. If we create a mechanism like patent pool, licensing would be much easier in the biological field as well. Various perspectives were shown as such. In the end, universities are not different from other patentees and they act under the premise that obtaining patent facilitates innovation.

Furthermore, the discussion covered the relation between competition and coordination as well as the issue whether the invention belong to faculty or university. Also, from the floor, a question was made concerning the possibility of patent pool by university. The discussions were conducted actively as a whole.

(Ichiro Nakayama)



RCLIP International IP Seminar: "Compulsory Licenses and Patent Working Requirement under India Patent Law"

(2011/7/8)

【Speaker】S. K. Verma, Professor of Law, University of Delhi; Visiting Researcher at Kansai University Institute of Legal Studies

The RCLIP International IP Seminar on July 8, 2011 invited Professor S. K. Verma at University of Delhi, who is a leading expert on Indian IP law, to present on "Compulsory Licenses and Patent Working Requirement under India Patent Law"

Due to transfer to product patent and oligopolistic drug market by the rising multinational companies, the price of patented drugs is getting higher in India. Out of critical concerns for public health, compulsory license (CL) regime currently becomes an issue in India. Professor Verma outlined CL provisions in Paris Convention (Art.5 A) and TRIPS Agreement (Art.30 and Art.31) as the framework of CL in international treaties. As CL regime in other jurisdictions, she introduced the current conditions in India after referring to the instances in the US, South America, and Brazil.

In India, CL is a topic of discussion. Many applications have been filed but no CL is issued under the Patents (Amendment) Act, 2005. CL is an issue as such for the following reasons. First, India has switched over from process patent to product patent by the Patents (Amendment) Act, 2005 to protect medical drugs or chemical materials. In addition, many Indian companies have been targeted for takeover by multinational companies recently, affecting generic drug market in India which has prospered. Concerns are that such takeover may lead to oligopolistic market, and companies are dictating prices for drugs critical for public health. There have also been strategic alliances between Indian and foreign drug companies. These companies may no longer be interested in applying for CLs. There is a concern that these MNCs may utilize

Indian companies to sell their high priced patented drugs in India.

Next, Professor Verma explained about CL provisions in Indian Patent Act. She stressed that the Act was legislated in accordance with the TRIPS agreement and Doha Declaration of 2001, in terms of the fact that the CL provisions are specifically designed to curb the monopoly rights of patentees, especially when the rights run counter to public health goals.

Sec. 83 outlines the main premise for issuing of CLs, based mainly on Article 7 and 8 of the TRIPS. There are four enabling provisions to issue CLs by the Controller: (1) Sec. 84- general CLs on an application, (2) Sec. 91- issue of CL for a related (dependent) patent on application, (3) Sec. 92- issue of CL upon notification by the Central Government (identical to Art. 31(b) of TRIPS provisions) and (4) Sec. 92A- issue of CL on application for manufacture and export of patented drugs under Doha Declaration (Para. 6).

Sec. 84 stated in (1) empowers the Controller to grant a CL on an application by any interested person after the expiration of 3 years from the date of grant of a patent. The grounds for granting CLs are: that the reasonable requirements of the public with respect to the patented invention have not been satisfied; or that the patented invention is not available to the public at a reasonable affordable price; or that the patented invention is not worked in the territory of India. Art.92 A is a provision only for medical products. It stipulates that CL can be issued for exports of generic drugs to meet public health emergency in countries that have insufficient or no manufacturing capacities (it is in accordance with the TRIPS Council Resolution of 31 August 2003). Several applications for CL were received under this provision, but none was admitted.

As judicial precedents, she introduced F.Hoffmann-La Roche Ltd. V. Cipla Limited (March 2008). The court refused to issue the injunction, referring to the US Supreme Court decision in eBay v. MercExchange [547 US 388 (2006)]. The decision was known as it admitted "CL judicially". The case was related to infringement of patent rights of Plaintiffs in the drug Erlotinib by the respondent, the generic drug manufacturer. Referring to the decision on eBay v. MercExchange, Delhi High Court enlisted the following three tests for the issuance of injunction; (1) existence of prima facie case, (2) balance of convenience, and (3) Irreparable hardship (and public interest). The Court refused to issue the injunction on the grounds that the patented products was imported into India and not manufactured, and that plaintiff's damage is assessable in monetary terms, but the injury to the public which would be deprived of defendant's product (which is affordable and manufactured locally) may lead to shortening of lives of many. The case is the first Indian case to reject the injunction on the ground of the high price of life saving drug. After that, many companies have filed applications for CL on the same ground.

Last, she explained about non-working of patent and domestic working requirements. According to the Annual Report of the Patents Office for 2009-2010, only 13% of all patents granted are actually being worked. Sec. 83 and Sec. 89 of Indian Patent Law require "patented inventions to be worked on a commercial scale in India without undue delay and to the fullest extent that is reasonably practicable". Non-working of a patent is a ground for revocation of a patent. In other words, central government or any interested person, after the expiration of two years from the date when first CL was granted, may apply to the Controller for an order revoking the patent. Grounds for revocation are: patented invention has not been worked in the territory of India; or reasonable requirements of the public from patented invention have not been satisfied; or patented invention is not available to the public at a reasonably affordable price. Controller has the power to seek information from a patentee or a licensee regarding the "extent to which the

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patented invention has been commercially worked in India" (Sec.146). In February 2010, the Controller issued a notice seeking such information. As per the data, most of the big Pharmas were found to be in default in providing details of working of their patents in India.

In July 2010, the government brought out a Discussion Paper on CL. The Paper discussed the issues related to royalty payable to the right-holder in the case of issuance of CL. It pointed out that no set formula on royalty payment in India presently. The issue of insufficiency of disclosure in the patent application was also raised, which can make the CL unworkable. In April 2011, the Government has concluded that the framework of the Indian Patents Act fully meets all obligations and provides adequate guidance for the issue of CLs. Hence, no additional guidelines are required.

Following the speech stated above, in the QA session, an active discussion took place on the issues including comparison with the decision on eBay and concrete conditions of filing application.

(Assistant Researcher Noriyuki Shiga)

The IP Precedents Database Project

IP Database Project: China

A survey is currently being conducted on the example of usage of the DB. We will advance the project this year planned with the collaboration of Chinese Professors.

(Global COE Research Associate Yu Fenglei)

IP Database Project: Korea

Currently 141 Korean IP precedents in total are placed at the RCLIP database. Aiming at adding more cases as well in the FY 2011, we are developing our plans with Korean collaborators.

(RC Lea Chang)

IP Database Project: Thailand

We are discussing with collaborators on the concrete plans of this year including case collection and translation. (RC Tetsuya Imamura)

IP Database Project: Taiwan

We will continue collecting precedents for the year of 2011, based on consultation with related parties

(Research Associate Akiko Ogawa)

IP Database Project: Indonesia

We will discuss with Attorney Fiona Butar-Butar on the creation of new data for this year.

(Research Associate Noriyuki Shiga)

IP Database Project: India

We are discussing with collaborators on the concrete plans of this year including case collection and translation.

(RCLIP Office Staff Chiemi Kamijo)

IP Database Project: Europe

We are discussing with collaborators on the concrete plans of this year including case collection and translation.

(RCLIP Office Staff Chiemi Kamijo)

Events and Seminars

As the JASRAC Open Lecture of 2011 "Urgent Issues Surrounding Copyright Infringement", four lectures will be consecutively held. The details will be announced at the RCLIP's website.

No.1 September 24, Saturday 13:30～17:30
"Constitutional Dimension of Copyright Law and Protection of Users"
【Place】Waseda Campus, Bldg 8, Room B107
(Japan-English Consecutive Interpretation)
【Moderator】Ryu Takabayashi, Professor of Waseda University

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【 Speaker 】 Christophe Geiger, Associate Professor of University of Strasbourg / Lea Chang, Assistant Protessor of Tokyo City University
【 Comment 】 Masahiro Kurita, Associate Professor of Ryukoku University

No.2 October 15, Saturday 13:30～17:00
"Modern Issues Surrounding Moral Rights"
Part II Moral Rights with the Perspective of Author
【Speech】 "Moral Right for Cartoonist"
【 Speakers 】 Machiko Satonaka, cartoonist, Professor of Osaka University of Arts, Intellectual Member of Property Strategic Headquarters, Cabinet Office, Member of the Cultural Affairs Council of the Agency for Cultural Affairs
【Commentator】Reiko Nagao, the Japan Writer's Association
Part II Modern Issues Surrounding Moral Rights (panel discussion)
【Panelists】Tatsuhiro Ueno, Professor of Rikkyo Univeristy / Ryoichi Mimura, former Judge of IP High Court; attorney at law
【 Moderator and Panelists 】 Eiji Tomioka, attorney at law / Tetsuo Maeda, attorney at law

No.3 November 19, Saturday 13:30～18:00
"Employee's Work and Copyright Contract Law under German Law"
Part I（13:30～15:30）
【Theme】Employee's Invention and Work: The Encounter of The Third System
【Speaker】 Prof. Dr. Christoph Ann, Technische Universität München
【Moderator】Toshiko Takenaka, Professor of UW Law School
【Comment】Ichiro Nakayama, Professor of Kokugakuin University
【Co-organizer】 Industry Alliances Division, Tokyo Medical and Dental University
Part II (16:00～18:00)
【Theme】Copyright Contract Law in Germany
【Speaker】 Prof. Dr. Jan Bernd Nordemann, Honorary Professor at the Humboldt University [BOEHMERT & BOEHMERT]
【 Moderator 】 Tatsuhiro Ueno, Professor of Rikkyo University
【Comment】 Kazuhiro Ando, Visiting Senior Researcher of IIPS-Forum, Waseda University
(Japan-English Simultaneous Interpretation)

No.4 December 3, Saturday 13:30～17:45
"Various Challenges under Copyright Law Surrounding Cloud Computing"
Part I (13:30～15:30)
【Theme】Overall discussion, various challenges concerning direct infringement and restriction of right
【 Moderator 】 Ryuta Hirashima, Tsukuba University
【Speaker】TBD
Part II (15:45～17:45)
【Theme】Provider's Responsibility Concerning Copyright Infringement—The Updated Trends and Reestablishment of Doctrine
【 Speaker 】 Yoshiyuki Tamura, Professor of Hokkaido University / Lea Chang, Assistant Professor of Tokyo City University / Toru Maruhashi, NIFTY Corporation
【 Moderator 】 Yasuto Komada, Professor of Sophia University

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