Patent Protection for Inventions in the Life Sciences and its Prospect

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Abstract

Patent protection for inventions in the life sciences is being a main topic in Japan's Intellectual Property Strategic Programs for some few years. While this paper picks up various topics in the life sciences on the basis of Intellectual Property Strategic Program 2009, it explains its present situation and comments on its prospect.

1. Introduction

The awareness regarding health of the general population has increased in hand with the trend towards an aging society. Consequently, the importance of patent protection for research and development in the life sciences is increasing.

The Intellectual Property Strategic Program 2009 determined by the Intellectual Property Strategy Headquarters on June 24, 2009 presents a policy statement as summarized below related to patent protection in the life sciences.

(1) Reviewing and clarifying the subject-matter of patent protection in the fields of cutting-edge medical technology. (Items No. 2, 3, 301)

(2) Reviewing the patent duration-extension system such as addition of innovative medicines that differ only with respect to the form of the agent used in an innovative formulation technology such as DDS.[1] (Item No. 5)

(3) Examination of the current situation of protection of use inventions related to functional foods etc. (Item No. 6)

(4) Construction and implementation of intellectual property strategies to appropriately obtaining rights and commercialize the results of iPS cell technologies in both domestic and foreign jurisdictions. (Item No. 22)

(5) Disseminating "Guidelines for Facilitating the Use of Research Tool Patents in the Life Sciences" and the construction of an integrated database related to research tool patents in the life sciences. (Item No. 30, 31)

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2. Innovation in the Life Sciences

Innovation in the life sciences is characterized by the fact that a single patent right in the life sciences could be more important than in other technical fields and this situation is spurred by the fact that substitute technologies to avoid the scope of such patent rights is normally difficult to develop.[2]

With a completion of the human genome draft sequence in June 2000, [3] and the declaration of the completion of the human genome project in 2003, there has been a paradigm shift in drug development over the last ten years. In other words, the function and three-dimensional structures of constitutive elements of the living body (i.e. receptors and physiologically active substances which are proteins) has been elucidated based on genomic information, thereby enabling the use of substances modifying functions as drugs. This is a new paradigm termed "genomic drug discovery." In comparison to the conventional pharmaceutical development where new drugs were found by chance, there is an expectation that pharmaceuticals can be developed efficiently. On the other hand, the necessity of large-scale R & D investment and the overlapping of drug targets have created new problems.

Furthermore, a principal characteristic of genomic drug discovery is that there exists a division of labor from upstream research (i.e. comprehensive collection of basic data such as determination of the sequence of genes, determination of the three-dimensional structure of proteins) to downstream research (i.e. development of pharmaceutics) , and that universities, public research institutes and startup companies conduct upstream research.[4]

The genetic information and three-dimensional structural information of proteins derived from the Human Genome Project must be useful as a tool for pharmaceutical development. However, there is not always a connection with pharmaceuticals which are the specific fruits of such research.

Where a single company conducts a series of research from upstream to downstream relevant to genomic drug discovery, it should file a patent application for only the pharmacologically active ingredient of the pharmaceutical which is the downstream research fruit (i.e. a substance modifying the function of the receptor or the physiologically active substance). However, universities and startup companies conducting only upstream research are actively trying to acquire patent rights with respect to intermediate products (such as gene-related information or research tools[5]) under the division of labor in this industry.

3. Coordination of Competing Rights and Interests between Upstream Researchers and Downstream Researchers

The coordination of rights and interests between upstream researchers (universities, public research institutions and startup companies) and downstream researchers (medical institutions and pharmaceutical manufacturers) in the life sciences has become an important problem in recent years.

The National Academy of Sciences (NAS) and the Organization for Economic Cooperation and Development (OECD) were the first to recognize this problem and made research and proposals with respect to a suitable balance between patent protection and exploitation in the life sciences. Furthermore in Europe, legislative revisions were made to limit the effect of genetic patents in order to guarantee freedom of research, diagnosis and treatment in medical institutions placed downstream.[6]

With a leading role played by the Japan Patent Office (JPO) in the context of the Co-operation Project of the Trilateral Patent Offices, comparative study has been carried out so that excessive patent protection is not granted to

gene-related inventions or inventions related to protein three-dimensional structure, and it has been confirmed at the Meetings of Patent Commissioners that strict examination standards should be applied in unison by the Trilateral Patent Offices.[7] The JPO amended the Examination Guidelines based on the report of this project.

In Japan, litigations have occurred from claims for injunction of patent infringement against downstream researchers by using patent rights from the results of upstream research.

In the decision[8] No. 1999 (Wa) 15238 of Tokyo District Court of December 20, 2001, the plaintiff alleged that an animal (model mouse for a human cancer) used in experiments in a certain national medical university infringed the patent right (Patent No. 2664261) of the plaintiff, and requested an injunction restraining use of the model mouse by the defendant. However, it was decided that the mouse of the defendant did not infringe the patent right and the claim for injunction was set aside. The decision was upheld on appeal.[9]

In the decision No. 2006 (Wa) 7760 of Osaka District Court of October 6, 2008, the plaintiff alleged that experiments for screening ligands of CCR5 by the defendant infringed a series of patent rights (Patent No. 3288384) related to chemokine receptor 88C (CCR5) gene of the plaintiff, and requested the injunction of drug discovery research related to the CCR5 ligand (AIDS therapeutic agent) by the defendant. However, since the patent rights of the plaintiff did not enjoy the priority claim under the Paris Convention and should be invalidated for lack of inventive step or novelty, it was determined that it was not possible to exercise patent rights pursuant to Article 104(3) of the Patent Act and the request for injunction was set aside.

"Various Problems related to the Facilitating the Use of Patented Inventions" as published by the Patent Strategic Planning Related Problems WG under the Industrial Structure Council in November 2004 confirms the view that research work using research tool patents does not fall under "experimental or research" in Article 69(1) of the Patent Act which limits the exercise of a patent, and confirms that a cautious approach should be taken to the use of an compulsory license system from the viewpoint of international cooperation and intellectual property policy of Japan.[10]

On the other hand, the Council for Science and Technology Policy made reference to the Guidelines of the OECD and the National Institutes of Health (NIH)[11] and formulated "Guidelines for Facilitating the Use of Research Tool Patents in the Life Sciences" in March 2007.

Although this Guidelines recommended the granting of a non-exclusive license on rational royalty making reference to the Guidelines formulated by the OECD in February 2006, it is not legally enforceable to the patent holder.

One of the characteristics of the life sciences could be that it is necessary to pursue design of the whole system by not only promoting innovation by endowing exclusive right such as patent right, but also taking into account the balance with the "public interest" of research, diagnosis, treatment and pharmaceutical development in medical institutions.

4. Emergence of iPS Cell (induced Pluripotent Stem Cell) Technology and Bioethics

In the life sciences, particularly in the field of regenerative medicine, ethical problems may form an impediment to research and development or the patent protection. For example, human ES cells (embryonic stem cells) having pluripotent characteristics are made by rupturing a fertilized egg of a human origin and therefore there is a risk of damage to "human dignity."[12] In particular, the preparation of cloned embryo required for regenerative medicine necessitates the rupturing of a fertilized egg whenever treating in order to introduce the genome of the patient, therefore it presents

problems with respect to bioethics.

In Europe with a prevailing mainstream of the Roman Catholic Church, this is a very sensitive issue and the European Patent Office (EPO) decided that inventions related to ES cells obtained by rupture of human embryos were contrary to "ordre public" or morality (EPC 53(a)) in the Enlarged Board of Appeal decision G2/06 (November 25, 2008). Furthermore in the United States with a mainstream of the Protestant churches, although patents are granted for human ES cells, patents are not granted for human embryos.

In Japan, although the "Basic Approach related to the Handling of Human Embryos" as adopted in July 2004 by the Expert Panel on Bioethics of the Council for Science and Technology Policy proposed a course of action to promote research using human embryos, specific guidelines were not yet to be prepared for some years after that.

In such a circumstance, in November 2007, Professor Shinya Yamanaka of Kyoto University succeeded in preparing an iPS cell which is a pluripotent cell similar to an ES cell from human skin cells.[13] This achievement was results of applying the success in a mouse[14] by the same researcher to a human. At the same time, a group at the University of Wisconsin lead by Professor Thomson also succeeded in preparing a human iPS cell[15] and competition in research and development of pluripotent stem cells is extremely fierce.

An iPS cell can be prepared without rupturing a human embryo in spite of the fact that it is a pluripotent stem cell having the same properties as an ES cells originating in a cloned embryo. Therefore, no problems arise with respect to bioethics. Indeed, the research results of Professor Yamanaka were worth receiving the blessing of the Holy Father.

In order to deal with global research and development competition for iPS cells, the Council for Science and Technology Policy in April 21, 2009 submitted a revision to the "Guidelines for handling of a specified embryo" with respect to details to approve the preparation of human cloned embryos. Furthermore on June 24, 2009, the Ministry of Education, Culture, Sports, Science and Technology announced an "iPS Cell Research Roadmap" stating specific targets such as timing of starting clinical research on the purpose of justifying large funding (¥14.5 billion for FY2009),[16] and it is trying to promote iPS cell research.

5. Patent Protection in the Field of Advanced Medical Technology

In the Intellectual Property Strategic Program 2008, appropriate patent protection in the field of advanced Medical Technology was decided to study in view of the acceleration of R & D competition around the world in the field including iPS cells. As a result of discussions in eight meetings of the Advanced Medical Patents Committee established under the Intellectual Property Strategy Headquarters, proposals were finalized on May 29, 2009 and were reported to the Intellectual Property Strategic Headquarters on June 24, 2009.

Researchers at universities and industrial circles had hoped for the general methods of medical treatment to be included as patentable subject matter in a similar manner to the United States. However, such inclusion into patentable subject matter of general methods of medical treatment was deferred from the viewpoint of "public interest" that restriction resulting from patent rights on the free diagnosis and treatment by doctors should be discouraged.

"On Patent Protection in the Field of Advanced Medicine" reported to the Intellectual Property Strategy Headquarters has proposed that (1) inventions for data collection method regarding the human body for the purpose of supporting final diagnosis, and (2) inventions characterized by the administration and dosage of a pharmaceutical substance or cell, should be added as new patentable subject matters, and also proposed (3) clarification for examination

standards related to iPS cell-related inventions.

(1) Inventions for data collection method regarding the human body for the purpose of supporting final diagnosis

For the purpose of harmonization with the patent systems of other developed countries, in order to enable comprehensive protection for inventions related to measuring devices using groundbreaking mechanisms or principles which may appear in the future and to enable appropriate protection for new technologies, a proposal was made to revise Examination Guidelines to include "inventions for human body data collection methods for the purpose of supporting final diagnosis" (methods of measuring the human body not including surgery, therapy, diagnosis ; e.g. principles and mechanisms for tomographic imaging using MRI, X-ray CT etc.) which are currently outside patentable subject matter.

According to the proposal, this would be a new revision of the Examination Guidelines since the last revision of April 2005, when the Examination Guidelines "Industrially Applicable Inventions" was revised and methods for controlling the operation of medical devices[17] were added as a new patentable subject matter.

The decision of the Enlarged Board of Appeal of the European Patent Office (EPO) G1/04 (December 16, 2005)[18] determined that the scope of an invention excluded from patentable subject matter as a method of diagnosis should be narrowly interpreted. In other words, only the inventions for a method including all four steps below are excluded from patentable subject matter as a method of diagnosis.

(i) A step for examination involving the collection of data

(ii) A step for comparison of the collected data with standard values

(iii) A step for finding of any significant deviation as a result of the comparison (i.e. symptom), and

(iv) A step for a medical judgment in which the deviation is attributed to a specific clinical picture

The step (iv) above is a purely intellectual exercise and therefore only combinations of steps (i) - (iii) preceding the step (iv) are recognized as an invention having a technical feature. In other words, although inventions for methods which include the judgment step (iv) by a doctor are excluded from patentable subject matter as a method of diagnosis, inventions for intermediate data collection not including the step (iv) are patentable subject matter.

In the revised Examination Guidelines (draft)[19] of the JPO, it is stated that inventions for human body data collection methods for the purpose of supporting final diagnosis are patentable subject matter and are not contrary to the first paragraph of Article 29(1) of the Patent Act, even when a step with an influence on the human body by a device is included, by taking into account the practices of the EPO[20].

Since methods of surgery or methods of therapy remain unpatentable, in steps for collecting data or samples from the human body, inventions associated with a surgical step, for example, incision or blood sampling, or a step for using a catheter or an endoscope inside the human body, are contrary to the first paragraph of Article 29(1) of the Patent Act. These practices are also consistent with the practices of the EPO.

Even with respect to data collection methods for the human body, inventions which are necessarily associated with surgery steps or therapy steps, or inventions which are indivisible from surgery steps or therapy steps are not patentable subject matter. These practices are consistent also with the decision of the Tokyo High Court No. 2000 (Gyo-Ke) 65 handed down on April 11, 2002. [21]

(2) Inventions characterized by Administration and Dosage of a Pharmaceutical Substance or Cell

For the purpose of promoting research and development of pharmaceutical substances which dramatically minimize the occurrence of side effects or greatly enhance the quality of life (QOL) of patients as a result of innovation with respect to "administration and dosage," a proposal was made to revise the Examination Guidelines in order to protect inventions with new administration and dosage of pharmaceutical substances as "product" inventions if such inventions show the effect exceeding beyond the expectation of the person skilled in the art.

According to the proposal, this would be the first revision of the Examination Guidelines since the Examination Guidelines "Medicinal Inventions" was implemented in April 2005.

In the inventions for the medicinal use up to that time, the novelty of claimed invention had not been denied when there is a difference on the "efficacy and effect" of a pharmaceutical and there is a difference on a patient group to be treated between the cited invention and the claimed invention. In the revised Examination Guidelines (draft),[22] even when there is no difference between the compound of the medicinal invention as claimed and the compound in the cited invention and there is no difference with respect to the applied disease (efficacy and effect), if the medicinal invention as claimed differ from the cited invention with respect to medicinal use of applying to a specific disease with a specific "administration and dosage" based on the attribute of the compounds, the novelty of the claimed invention is not denied.

In a package insert associated with the sale of a pharmaceutical product based on the Pharmaceutical Affairs Act, "administration and dosage" is stated in addition to "efficacy and effect." Therefore, there is a demand among medical practitioners and patients in R & D of medicines for the purpose of a dramatic minimizing the occurrence of side effects or greatly enhancing the quality of life (QOL) of a patient as a result of innovation with respect to "administration and dosage." In order to promote such innovation, the Examination Guidelines is revised so that an invention for pharmaceutical products with a new administration and dosage which shows the effect exceeding beyond the expectation of the person skilled in the art should be protected as a medicinal invention in the "product" category.

In the practice of the revised Examination Guidelines, a patent should not be granted to an invention which lacks an inventive step such as an invention within a variation of "administration and dosage" performed at the discretion of a doctor. In the revised Examination Guidelines (draft), in order to solve problems that are well known to a person skilled in the art such as the increase of a medicinal effect, the reduction of a side effect or the improvement in drug compliance, it is stated that the optimization of "administration and dosage" is among exercise of ordinary creativity of a person skilled in the art. In case where the advantageous effect compared with the cited invention can be foreseen by a person skilled in the art, the inventive step is usually denied.

In the EPO, the Enlarged Board of Appeal (G2/08)[23] is currently considering the matter based on decision T1319/04 (April 22, 2008) which casts doubt on Decision T1020/03 (October 29, 2004) which recognized the novelty of a medicinal invention (Swiss-type claim) characterized only by a dosage regimen.

In Japan, there is no judicial precedent in relation to the above practice focusing on the novelty of a medicinal invention characterized only by "administration and dosage."[24]

6. Review of the Extension System of Patent Duration for Pharmaceuticals

As symbolized by the 2010 Problem[25] for pharmaceutical substances, the development of a novel pharmaceutical substance based on the discovery of a novel active ingredient (pharmacologically active ingredient) has

been getting extremely difficult. Prior to the decision at the EPO, Japan had revised Examination Guidelines to protect medicinal inventions characterized only by "administration and dosage." Consequently, there appears to have been a change in the R & D of pharmaceutical substances from research aiming at novel active ingredients to the development of innovative formulation technology such as DDS.

The extension system of the duration of patent rights for pharmaceutical substances enables recovery of the period during which the patent right could not be exploited due to the time required for the approval of manufacturing and marketing under the Pharmaceutical Affairs Act for the purpose of ensuring the safety. The recovery of this period takes the form of extending the duration of patent rights (Article 67(2) of the Patent Act and Article 3 of the Patent Act Enforcement Order). The effect of extended patent rights is limited to specified "product" and "use" being the subject of procedures under the Pharmaceutical Affairs Act (Article 68 *bis* of the Patent Act).

In current Examination Guidelines, it is interpreted that a "product" is an "active ingredient" and a "use" is an "efficacy and effect", and therefore it is described that "an application for patent term extension based on a later approval of a pharmaceutical with active ingredient and efficacy/effect both identical to those specified in another earlier approval (differing only in dosage form, manufacturing process etc.) shall be refused, since obtaining of the later approval is not considered necessary in the working of the patented invention." [26] In suits against appeal decisions, the Intellectual Property High Court and its predecessor, the Tokyo High Court has upheld this position.[27]

However, in three decisions[28] Nos. 2008 (Gyo-Ke) 10458 – 10460 handed down by the Intellectual Property High Court on May 29, 2009, it was decided that, a "product" is not only an "active ingredient" but may also be interpreted on the specific level of a "pharmaceutical product" specified by an "article" which is subject to procedures under the Pharmaceutical Affairs Act, and non-inclusion of a "pharmaceutical product" of the previous official action within the technical scope of the patent right at issue did not constitute a reason for rejection under Article 67 *ter* (1)(i).

Since an opportunity for extension of patent duration is created if there is a difference in the drug formulation even when the "active ingredient" and the "efficacy and effect" are the same as the previous official action, there is an advantage for the strengthening of patent protection among parties developing innovative formulation technology such as DDS techniques currently under rapid development. From the viewpoint of "use", as discussed above, since patent rights characterized not only by "efficacy and effect" but also by "administration and dosage" will be able to be granted under the revised Examination Guidelines (draft), the approach of interpreting on the specific level of a "pharmaceutical product" specified by an "article" may create a room for extending the opportunity for extension of patent right for medicinal inventions characterized only by a "administration and dosage." When viewed in this manner, there are problems in the above judicial decisions that are in disparity with the current practice of the JPO and also with the previous judicial decisions supporting the JPO practice. However, if viewed as a proposal relevant to the creation of a new system which meets current needs, these decisions are legally organized well.

As a result, the three decisions above are clearly inconsistent with previous judicial decisions which were maintained for 20 years since 1988 and which support the current practice that a "product" is an "active ingredient" and a "use" is an "efficacy and effect" and consequently, the JPO appealed to the Supreme Court.

Although the expansion of opportunities for extension of patent duration into formulation technology is good news for patentees, as a necessary consequence of the creation of a new system, the effect of the extended patent right is reduced from the scope traditionally prescribed by "active ingredient" and "efficacy and effect" to the specific level[29] of

an "article" which are given marketing approval under the Pharmaceutical Affairs Act, and this may not be palatable for those patentees who do not place importance on formulation technology.

In any event, the current practice in Japan is to recognize extension of patent duration when either of the "active ingredient" or "efficacy and effect" is novel in the approval under the Pharmaceutical Affairs Act. This approach is in contrast to the practice in the United States and Europe where extension of patent duration is only granted when the "active ingredient" is new. The current practice in Japan is considered to have promoted research and development with respect to the "efficacy and effect" of pharmaceutical substances so far. Hereafter, in spite of restriction with respect to the effect of patent right, sufficient consideration must be given to whether or not to adopt a new system for the further promotion of research and development of "formulation technology."

7. Functional Foods

The increasing attention to health in the Japanese population has resulted in a demand for everyday foods to include functions for maintaining and recovering physical conditions. As a result, there are increasing problems surrounding the patent protection of functional foods represented by the Food for Specified Health Use (FOSHU)[30] which qualify for the designation of "use for maintaining health" based on the Health Promotion Act.

Functional foods which are capable of classification as new "products" on the basis of a difference in composition from existing foods, already form part of patentable subject matter.[31] On the other hand, functional foods which cannot be classified as a product different from existing foods do not provide a new use even when defining the use thereof according to the current Examination Guidelines, and therefore lack novelty.[32]

Since there is no obligation of display on functional foods for "use for maintaining health" attached as a package insert to pharmaceutical products which display "efficacy and effect" and "administration and dosage," there is only a weak basis for product distinction to form the premise of use invention.[33] Even if there is no display of "use for maintaining health" as a Food for Specified Health Uses (FOSHU), since there is an equivalent advertizing effect by merely publishing experimental data confirming an "efficacy and effect" on the Web or in academic journals, it is necessary to examine the significance of the existence of patent rights and their scope of effect. Furthermore, it is also necessary to consider the fact that many functional foods are health foods that are not capable of falling within the scope of FOSHU.

In any event, cautious consideration should be necessary from the viewpoint of "public interest" so that existing food manufacturers could not be caught up in the calamities of needless patent litigation.

8. Conclusion

This paper has surveyed present situations and problems of patent protection in the life sciences centering on the Intellectual Property Strategic Program 2009. Since the development of technologies in this area is extremely rapid and their effect on society is very great, there may well be a continuing stream of issues requiring consideration.

Research and development in the life sciences is associated with the life and health of the general population and therefore in addition to the recovery of R & D investment by inventors and the promotion of innovation, there is a need to go forward keeping in mind the "public interest" from the viewpoint of society as a whole.

Finally, the proper functioning of the patent system and its practice (Examination Guidelines) is expected to play

a role in the on-going creation of superior inventions in Japan and in the improvement of living standards.

Notes

[1] Drug Delivery System (DDS) is a system for the application of a required therapeutic agent to a required site at a required time (artifice or technique) and is an extremely important approach to the method of treatments using pharmaceuticals.

[2] "Guidelines for Facilitating the Use of Research Tool Patents in the Life Sciences" prepared by Council for Science and Technology Policy (March 1, 2007) indicates that "most patents for research tools are applicable to various purposes and are helpful in promoting research. However, at the same time, they are often less substitutable."

[3] Nature, Vol. 409, No. 6822 (15 Feb. 2001) was a special edition dedicated to the completion of the human genome draft sequence.

[4] Koichi Sumikura, "Human genome and patents," Tokkyo Kenkyu (Patent Studies). No. 31 (2001) pp. 28.

[5] A research tool refers to all tools used in a laboratory by a researcher. More specifically, it refers to model animals such as genetically modified mice, reagent chemicals and equipment such as PCR, methods such as screening, databases or software, etc.

[6] Akiteru Tamura, "Patent protection for inventions related to human genes," Jurist, No. 1296 (2005) pp. 118.

[7] Comparative studies on inventions related to genes whose functions were inferred based on homology search published on November 2000 (Project B3b), comparative studies on reach-through claims published in November 2001 (Project B3b), comparative studies on inventions related to the 3-D structure of proteins published in November 2002 (Project WM4), etc. These reports are published on the JPO HP and the Trilateral websites.

[8] Hanreijiho No. 1787, pp. 145, Hanrei Times No. 1101, pp. 242.

[9] Tokyo High Court, Case No. 2002 (Ne) 675, October 10, 2002, Hanrei Times No. 1119, pp. 215.

[10] In Toshifumi Hienuki, "Biotechnology and Competition Policy in Japan: the Problems of License Agreements on Research Tool Patents," Intellectual Property Law and Policy Journal, Vol. 9 pp. 1 (2005), it is indicated that "This has imposed severe hardship on the Japanese pharmaceutical industry."

[11] The OECD has established "Guidelines for the Licensing of Genetic Inventions" in February 2006. The NIH has also issued guidelines for disseminating research tools arising from government-funded R&D, and has disclosed information on the research tools retained by NIH, etc., with the aim of promoting the use thereof.

[12] "Act on Regulation of Human Cloning Techniques, etc. (Law No. 146 of 2000)" enacted January 6, 2001 prohibits the preparation of human clones for the reason that it will have a serious influence on "the preservation of human dignity."

[13] Cell, Vol. 131, pp. 861, November 30, 2007.

[14] Cell, Vol. 126, pp. 663, August 25, 2006.

[15] Science, Vol. 318, no.5858, pp. 1917.

[16] The budget for FY2009 was approximately ¥4.5 billion with a supplementary budget for FY2009 of ¥10 billion.

[17] The method for controlling the operation of a medical device is expressed as a method for a function provided with the medical device itself. A method including in the claims (1) a step for acts performed by a doctor or (2) a step of operation on the human body using the device is not the method of operating a medical device within the meaning as used herein.

[18] Decision T385/86 has placed a narrow interpretation on the previous provision EPC 52(4), and has shown that a method of providing an intermediate result is determined to be patentable. On the other hand, Decision T964/99 has determined that even though a step included in the method has a technical feature and provides intermediate data, in the event that a step is included which acquires a sample from the human body, such a method is unpatentable with respect to the previous provision EPC 52(4). Decision G1/04 drew a line under the debate with respect to the conflicting decisions. The previous provision EPC 52(4) has been prescribed as an exception to patentability 53(c) in the EPC2000 effective on December 13, 2007.

[19] The draft was published on the JPO HP on August 6, 2009 with invitation for public comments. The finalized revised Examination Guidelines have been applied to the applications that are examined on and after November 1, 2009.

[20] EPO Guidelines C-IV, 4.8.1.

[21] Hanreijiho, No. 1828, pp. 99.

[22] The draft was published on the JPO HP on August 6, 2009 with invitation for public comments. The finalized revised Examination Guidelines have been applied to the applications that are examined on and after November 1, 2009.

[23] The main point discussed in the Enlarged Board of Appeal (G2/08) is whether or not to grant a patent to an medicinal invention characterized only by a dosage regime subject to the provisions 53(c) and 54(5) in EPC2000.

[24] In Decision No. 2005 (Gyo-Ke) 10818, March 1, 2007, the Intellectual Property High Court refused novelty and inventive step due to the fact that the similar statement was present in the cited invention although the claim was specified by administration and dosage.

[25] This refers to a problem that around 2010, patent rights for blockbuster drugs will simultaneously expire in the pharmaceutical industry with the risk of a grave effect on the income of leading pharmaceutical makers.

[26] Refer to 3.1.1(3) of the Examination Guidelines Part VI "Patent Term Extension."

[27] For example, see Tokyo High Court, Case No. 1998 (Gyo-Ke) 361, February 10, 2000, Intellectual Property High Court, Case No. 2005 (Gyo-Ke) 10345, October11, 2005, Intellectual Property High Court, Case No. 2006 (Gyo-Ke) 10311, July 19, 2007.

[28] Decision Nos. 2008 (Gyo-Ke) 10458 and 10460 related to a pain killer using morphine hydrochloride as an active ingredient. The prior art pain killer has a dosage of 6 times per day whereas the pain killer at issue is a sustained-release preparation with a dosage of once per day. Decision No. 2008 (Gyo-Ke) 10459 relates to a therapeutic agent for breast cancer which has an active ingredient of leuprorelin acetate and is a sustained-release preparation which is injected once in 12 weeks in contrast to the prior art which is injected hypodermically every four weeks.

[29] Decision Nos. 2008 (Gyo-Ke) 10458 - 10460 affirms the Doctrine of Equivalents by determining that "It is reasonable that an article evaluated as substantially identical or as equivalent is included in light of the common understanding in the technical field."

[30] Food for Specified Health Uses (FOSHU) is a food recognized to reduce a health risk resulting from an inappropriate lifestyle. Such foods are allowed to display "use for maintaining health" as a function related to health based on Article 26 of the Health Promotion Act by the Minister of Health, Labour and Welfare.

[31] There are patents recognizing novelty due to the difference in composition in comparison with an existing food, for example, "Healthier" drink of the Kao Corporation or "Kuro Uroncha" drink of Suntory.

[32] Refer to Examination Guidelines Part II, Chapter 2, "Novelty and inventive step" 1.5.2.(2) ②Example 5.

[33] In Decision No. 2006 (Gyo-Ke) 10227, November 29, 2006, the Intellectual Property High Court recognized a difference in the use invention since there was a recognition as a different type of product based on a market research between the cited invention "cosmetic for skin whitening" and the claimed invention "cosmetic for wrinkle prevention".