Future Issues of the Intellectual Property System in Japan in Consideration of a Decade of Pro-Patent Policy

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Abstract--**In Japan, the Intellectual Property Basic Act entered into force in March 2003. Over the last decade, a pro-patent policy has begun to be rapidly promoted in accordance with the principles of the Basic Act with the objective of creating an intellectual property-based nation. In particular, reforms of the legal system such as the Patent Act have been promoted, while regulations have been enhanced and strengthened with respect to the creation, protection, and utilization of intellectual property. Many issues remain, however, and it will be necessary in the future to promote legal system reforms in order to strengthen competitiveness and achieve international harmonization. Japan has been advancing several intellectual property policies as pro-patent policies for past ten years as above. However, in other countries, there are some trends against pro-patent policies. In this paper, two cases (India and U.S.A.) are focused as trends against pro-patent policies, and discussed as comparative study. In the future, Japan should internationally advance pro-patent policies in consideration of those trends against pro-patent policies.**

I. INTRODUCTION

Ten years have passed since the Intellectual Property Basic Act entered into force in March 2003. A pro-patent policy has rapidly begun to be promoted over the last decade in accordance with the principles of the Basic Act, with the objective of creating an intellectual property-based nation. As a result, various reforms of intellectual property legislation have been carried out, with a key focus on the revision of the Patent Act.

Looking back over transitions in intellectual property legislation over the last ten years, this paper discusses the background against which new systems were introduced and existing systems revised, as well as the effects thereof. In addition, it examines what kind of legal system Japan should build in order to strengthen competitiveness and achieve international harmonization. Moreover, it discusses changes in examination guidelines and systems relating to examination, as well as transitions in legal system reforms in other countries, and examines the direction that should be taken in the future.

II. THE BEGINNING OF LEGAL SYSTEM REFORMS AIMED AT CREATING AN INTELLECTUAL PROPERTY-BASED NATION

Then-Prime Minister Koizumi's February 2002 policy statement on creating an intellectual property-based nation was the catalyst for the enactment and entry into force of the Intellectual Property Basic Act, the establishment of the Intellectual Property Strategy Headquarters, and the formulation of the Intellectual Property Strategic Program which set into motion a series of legal system reforms aimed at making Japan an intellectual property-based nation.

A. Enactment and Entry into Force of the Intellectual Property Basic Act

The Intellectual Property Basic Act entered into force in March 2003, with the objective of promoting measures focused on the creation, protection and exploitation of intellectual property. Japan's economic stagnation during the 1990s (the lost decade) can be cited as a factor behind the enactment of the Intellectual Property Basic Act. At the time, amid the rapid economic growth of developing countries – primarily those in Asia – Japanese companies were faced with the necessity to switch from a conventional management strategy focused on making production systems more efficient to one that featured a high regard for added value. Consequently, the importance of intellectual property – above all, patents – was on the increase. Accordingly, the Intellectual Property Basic Act was enacted and entered into force, and measures concerning the creation, protection, and exploitation of intellectual property began to be promoted.

In general, a basic act is a law enacted in order to set out the basic policy in a specific administrative field. The Intellectual Property Basic Act sets out the basic policy on intellectual property policy, and following its enactment, the Cabinet's Intellectual Property Strategy Headquarters was established in accordance with its provisions and an Intellectual Property Strategic Program began to be formulated each year, marking the start of the intensive, systematic promotion of measures concerning the creation, protection, and exploitation of intellectual property. At the time, the enactment of the Intellectual Property Basic Act was an initiative unique to Japan, without precedent in any other country, so one could say that it was the most important legal system reform aimed at achieving an intellectual property-based nation.

B. Establishment of the Intellectual Property Strategy Headquarters

The Intellectual Property Strategy Headquarters was established within the Cabinet in May 2003, in accordance with the provisions of Article 24 of the Intellectual Property Basic Act. The main task of the Intellectual Property Strategy Headquarters was to promote the formulation and implementation of the Intellectual Property Strategic Program; expert panels focused on specialized areas have also been established, engaging in a variety of discussions to date. At present, there are two expert panels – the Expert

Panel to Enhance Competitive Strengths and Drive International Standardization and the Expert Panel to Strengthen Content – that discuss various issues within their respective areas of specialism.

The Prime Minister serves as Director of the Intellectual Property Strategy Headquarters, the membership of which consists of Ministers of State and other senior government figures. Consequently, the establishment of the Intellectual Property Strategy Headquarters resulted in strong efforts to promote reforms of intellectual property legislation via a top-down policymaking process. Given that intellectual property legislation has been characterized by provisions targeting a wide range of administrative fields spanning a variety of ministries and agencies. The top-down policymaking process is an effective technique for counteracting the harmful effects of the bureaucratic sectionalism inherent in the intellectual property field. The annual compilation of the Intellectual Property Strategic Program, which serves as an action plan that cuts across ministries and agencies, is unquestionably one of the fruits of this approach.

C. Formulation of the Intellectual Property Strategic Program

In accordance with Article 23 of the Intellectual Property Basic Act, the Intellectual Property Strategic Program has been formulated each year since 2003, setting out the direction to be taken that year in administrative matters concerning intellectual property. One feature of the Intellectual Property Strategic Program is the highly practical nature of the measures that it sets forth as it breaks down measures concerning the creation, protection, and exploitation of intellectual property by policy area, and details the specific measures to be taken – as well as indicating the names of the ministry or agency that is responsibility for an individual policy area.

A great many measures from the Intellectual Property Strategic Program have been implemented, including the establishment of the Intellectual Property High Court (Ministry of Justice, 2004) and the strengthening of penalties for violations of the Patent Act (Ministry of Economy, Trade and Industry, 2006). Thus, many of the measures implemented in the intellectual property field over the past decade have actually come to fruition as a result of their inclusion in the Intellectual Property Strategic Program. One can see, therefore, that the program has played a part in setting the pace of reforms aimed at creating an intellectual property-based nation. Similar to the Intellectual Property Basic Act, moreover, the formulation of the Intellectual Property Strategic Program was an initiative without precedent in any other country at the time, serving as an effective measure aimed at creating an intellectual property-based nation.

III. TRANSITIONS IN LEGAL SYSTEM REFORMS AIMED AT CREATING AN INTELLECTUAL PROPERTY-BASED NATION - FOCUS ON REVISIONS OF THE PATENT ACT -

The legal system in the intellectual property field has undergone a variety of reforms in accordance with the Intellectual Property Strategic Program, guided by the philosophy of the Intellectual Property Basic Act. In particular, the legal system has been enhanced substantially in terms of the importance attached to intellectual property, with a particular focus on revisions of the Patent Act.

A. Legal System Reforms Aimed at Improving Dispute Resolution

Courts, as well as the Trial and Appeal Department of the Japan Patent Office, play a key role in the resolution of disputes surrounding intellectual property rights. Swift and accurate trial examinations by the courts and the Trial and Appeal Department are effective in strengthening the competitiveness of companies that make use of patents in their business.

In April 2005, the Intellectual Property High Court was established to serve as a specialist court for litigation relating to intellectual property rights. As a result, in intellectual property litigation (appeals) in Japan, trial examination began to be carried out by a specialist body in the form of the Intellectual Property High Court. Due in part to the effects of the expert advisor system and the judicial research official system, court expertise in the intellectual property field has increased – which has in turn enabled swifter, more accurate trial examination to be carried out. This is one of the most important legal system reforms aimed at creating an intellectual property-based nation.

With regard to the trial system, the revision of the Patent Act in 2003 resulted in the abolition of the opposition system and its integration/consolidation into the new system of trial for invalidation. This revision sought to reduce both the time taken to resolve disputes and the burden on the parties concerned, and appears to have yielded some positive results in terms of improving dispute resolution. As the opposition system was easier to use than the system of trial for invalidation, however, in terms of the fact that the opponent did not have to be involved as a party and the fees were comparatively cheap, there are those who see the abolition of the opposition system and resultant loss of a simple means of challenging the validity of defective patents as problematic. Following this revision, moreover, the USA introduced the "post grant review" system, which is similar to the opposition system, so the rights and wrongs of abolishing the opposition system are also subject to debate from the perspective of the international harmonization of the patent system. Accordingly, the introduction of a post grant review system is currently being considered by the Industrial Structure Council's Intellectual Property Policy Committee (Patent System Subcommittee) to serve as a system similar to that of

the opposition.

If the introduction of a post grant review system resulted in a return to the situation that existed before the 2003 revision, the problems experienced at that time would be replicated. If a post grant review system is to be introduced, consideration should be given to the purpose of the 2003 revision of the Patent Act – bearing in mind the relationship to the system of trial for invalidation, for example – and the introduction of a different system that improves upon the old opposition system.

Additionally, the 2011 revision of the Patent Act created an opportunity for correction in trials for invalidation based on the opinion of the panel of trial examiners (preliminary trial decision), as well as prohibiting the filing of a request for a trial for correction after a lawsuit has been filed. It is anticipated that this will promote improvements in the inefficient situation that arises when an appeal trial is demanded to correct the content of patent rights subject to dispute after a lawsuit has been filed for revocation of a decision to invalidate a patent – resulting in the case being referred back to the Japan Patent Office. Moreover, with regard to the irrevocable appeal decision in a trial for invalidation, even parties other than those concerned with the trial in question are not permitted to challenge patents on the basis of identical facts and evidence, so revisions such as permitting trials to be instituted by parties other than those concerned in the trial in question were introduced in order to eliminate the issue of rights being impeded by a third party's trial.

Curbing counterfeit goods and piracy is also vital in order to improve dispute resolution. In the 2006 revision of the Patent Act, "exporting" was added to the definition of "working" an invention, with the objective of preventing the proliferation of counterfeit goods and pirate copies. Additionally, "acts of possessing...for the purpose of assigning" were added to "acts deemed to constitute infringement", while the penalties for the infringement of rights were strengthened. All laws relating to industrial property rights have been revised in this way[1)], with the revisions expected to achieve widespread suppression of counterfeit goods and pirate copies. Japan already has extremely severe penalties for infringement, however, imposing long periods of imprisonment with work and high fines, so a cautious approach will be required when considering further tightening of penalties in the future.

B. Legal System Reforms Aimed at Promoting the Use of Rights

In order to create an intellectual property-based nation, it is important to achieve enhancements relating to laws that seek to encourage the effective use of intellectual property rights[2)]. In particular, agreements for the popularization of licenses (permission to work a patent) are effective in promoting open innovation, so legal system reforms have been promoted to this end[3)].

In the 2008 revision of the Patent Act, provisional licenses (provisional exclusive licenses and provisional non-exclusive licenses) were prescribed as the object of licensing at the patent application stage, and a registration system to protect licensees was created with the objective of encouraging the strategic use of intellectual property rights. This revision has also made it possible to ensure that licenses are effective against a third party through registration of provisional licenses at the application stage, so it is anticipated that this will increase incentives to create license agreements at the application stage. This would seem to have had some positive effects under the current situation, wherein it takes a comparatively long time for patent rights to be established.

On the other hand, the non-exclusive license registration system gave rise to some concerns in practice. Specifically speaking, since the facts of registration are made public, the number of non-exclusive licenses actually registered was low[4)]. Accordingly, the 2011 revision of the Patent Act stipulated that a license would be effective against a third party even if a non-exclusive license (including provisional non-exclusive licenses) is not registered. This has curbed the risks resulting from the assignment of patent rights, and it is anticipated that this will increase incentives for licensing.

In terms of the situation in other countries, the systems in the USA and Germany are the same as that in Japan following the revisions (in which licenses are effective against a third party as a matter of course), while the UK and France have systems wherein licenses are effective against third parties with knowledge of the absence of registration of a non-exclusive license. The licensing system therefore differs by country, so further international harmonization of the approach to protecting license agreements should be pursued in the future in order to encourage global licensing activities by companies.

Although it is possible in Japan to disclose one's willingness to assign or license rights via the Patent Gazette or the Patent Licensing Information Database, there is no system of incentives for making such disclosures. By contrast, countries such as the UK and Germany have introduced systems for signaling willingness to license rights (the so-called "License of Right" system), offering reductions in the patent maintenance fee for a patent if the holder registers their willingness to license it. The introduction of this kind of system should be considered in Japan in the future in order to encourage the effective use of patents[5)].

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1) "Possession for the purpose of assignment or delivery" was already prescribed as an "act deemed to constitute infringement" in the Trademark Act.

2) Intellectual Property Strategy Headquarters, "Intellectual Property Policy Vision", June 2013, Chapter 2

3) Japan Patent Office, "Annual Report (FY2010)", June 2010, part 2, Chapter 1

4) Approximately 90% of companies, etc. responded that their non-exclusive license registration rate was 0% or less than 1%. (Press release concerning the 2011 revision of the Patent Act / Japan Patent Office)

5) Intellectual Property Strategy Headquarters, "Intellectual Property Strategic Program 2008", June 2008, Chapter 3.

C. Legal System Reforms Aimed at Appropriate Protection of Inventions

In order to strengthen competitiveness with research and development at its core, appropriate protection of inventions – the fruits of that research and development – is vital. Accordingly, reforms of the legal system associated with the patent system have been carried out with the aim of providing more appropriate protection for inventions, through such means as improving the convenience of procedures undertaken by applicants, and preventing the misuse of provisions concerning procedures.

In the 2006 revision of the Patent Act, restrictions on filing periods for divisional applications were relaxed, permitting the division of applications "for a certain period after the examiner's decision of grant or refusal", as well as "within the allowable time limit of amendments". The purpose of this revision was to provide more ample protection for inventions included in descriptions, etc. in patent applications, as there had hitherto been cases in which the claim at the time of the examiner's decision of grant was not effective enough, as well as cases wherein an examiner's decision of refusal was issued because the invention was unable to be described precisely in the claim.

Similarly, with the objective of preventing misuse of divisional applications, the 2006 revision of the Patent Act imposed a limit on amendments in cases where – following the examination of a divisional application – the applicant has already been notified of the reason for refusal at the time of the examination of the original application, and that reason is to be applied unaltered. This is because the applicant has already been notified of the reason for refusal, and is similar to the limit that applies in the event of a "final Office Action" (even if this is the first Office Action).

In the 2008 revision of the Patent Act, the time limit for filing a request for a trial against an examiner's decision of refusal was extended from 30 days to three months. The purpose of this revision was to eliminate the problem whereby the comparatively short time limit for filing a request for a trial under the conventional system meant that it was not possible to make proper judgments about appropriate requests for trials based on, for example, the content of amendments of the description. In addition, the time limit for filing a request for a trial against an examiner's decision of refusal was extended from 30 days to three months in the Design Act and the Trademark Act.

As described above, the Patent Act has been revised because improving the convenience of procedures carried out by applicants and preventing the misuse of provisions concerning procedures are crucial in providing appropriate protection for inventions. Such amendments of provisions concerning procedures often result in the revision of laws following deliberations in response to requests from users. In the future, it will continue to be important to facilitate proactive exchanges of opinions between the Japan Patent Office and users.

The 2011 revision of the Patent Act amended the exception to the lack of novelty provision, putting in place a system that makes it possible to acquire patent rights even after an invention has become public, as long as the inventor him- or herself published it, irrespective of the form that publication took. Introduced with the objective of improving convenience for users, this revision of the Act has expanded the scope of inventions for which patents can be granted, even after they have been published, and it is expected that it will provide appropriate protection for inventions.

There are many differences between Japan, the USA, and Europe in terms of the application of the exception to lack of novelty. Whereas in Japan this applies where the period from the date of publication by the inventor to application for a patent is six months, this period is 12 months in the USA, while in Europe, it only applies if the invention has been published at an official international exhibition. Under the European system in particular, publication by means of a paper or at an academic society meeting is not permitted as an exception to the lack of novelty, as this constitutes a barrier to universities filing applications in Europe regarding inventions, etc. This problem has been discussed internationally for some time by such bodies as WIPO's Standing Committee on the Law of Patents (SCP). It is one of the most serious outstanding issues relating to patent applications in Japan, the USA, and Europe, so one hopes that the system will be harmonized as soon as possible.

D. Legal System Reforms Aimed at the Prompt Acquisition of Rights

The shortened examination request period introduced in the 1999 revision of the Patent Act (from seven to three years) began to be applied to applications filed in October 2001 or thereafter in order to expedite the acquisition of rights. It has actually brought about an increase in the number of requests for examination, however, thereby prolonging the waiting period for examinations – and causing concerns that this situation will diminish the competitiveness of companies using patents in their business.

One legal system reform aimed at expediting patent examination is the revision of the system of patent-related fees. More specifically, the 2003 revision of the Patent Act reduced application fees and patent fees, while increasing fees for requests for examination, simultaneously alleviating the total cost per patent. The objective of this was to expedite patent examination by curbing futile requests for examination.

The reform of the utility model system is another legal system reform aimed at expediting patent examinations. Applications to register a utility model have a substitution effect on patent applications, curbing them by encouraging applications for utility model registration, and thereby contributing to patent examination expedition. The 1993 revision of the Utility Model Act created a system that permitted registration without substantive examination, but the number of applications for utility model registration subsequently declined considerably. Accordingly, the 2004

revision of the Utility Model Act extended the term of utility model rights from six to ten years, with the objective of making the utility model system more attractive. Additionally, the Patent Act was revised to make it possible to switch to a patent application even after registering a utility model. These legal revisions did bear fruit to some extent, with the number of applications for utility model registration increasing in 2005 by 43% compared with the previous year. Numbers fell again the next year, however, and by 2011, had reached about the same level as in 2004 before the revision was implemented. One could say that there is room for improvement in the existing utility model system, which could be made more attractive. In addition, as of 2011, the number of technical opinions prepared by examiners had fallen substantially, reaching about half the level seen in 2004. Consequently, deliberations are required with a view to improving the legal system, including provisions relating to the exercise of rights.

E. Legal System Reforms Aimed at International Harmonization

In the 2003 revision of the Patent Act, the requirement for unity of invention was harmonized in line with international standards. More specifically, the requirement for unity prescribed in the Patent Cooperation Treaty (PCT) was introduced in domestic law, with the stipulation that inventions that satisfy the requirement for unity shall be two or more inventions with a "technical relationship in which two or more inventions must be linked so as to form a single general inventive concept by having the same or corresponding special technical features among them." PCT is an effective system for the acquisition of global rights, and this revision further increased the convenience of PCT.

In the 2006 revision of the Patent Act, a provision was introduced that prohibited amendments that turn an invention into a separate invention with different technical features (prohibition of shift amendments). More specifically, the revision prohibited amendments made after receipt of an Office Action, seeking to turn the invention described in the claim into a separate invention with different technical features, as well as making such amendments a reason for refusal (or, if received after the final Office Action, for dismissal of an amendment). Under the system in place hitherto, it was possible to amend a claim after it had been subject to an Office Action, and to turn it into a separate invention with different technical features. Such amendments were not permitted, however, under the European and US systems. The prohibition of shift amendments was a revision of the system aimed at international harmonization of provisions on the restriction of amendments.

Moreover, the Trilateral Offices (official patent offices of Japan, the USA, and Europe) reached an agreement in November 2007 concerning a common form for the descriptions, claims, abstracts, and drawings that can be used for patent applications among all three offices (the Common Application Form). The Ordinance for Enforcement of the Patent Act was subsequently, revised, and applications using the Common Application Form began to be accepted on January 1, 2009. The form is accepted by any of the Trilateral Offices, and no amendments will subsequently be requested so it is anticipated that this will increase convenience and reduce costs when filing patent applications with the Trilateral Offices.

Amid the promotion of such legal system reforms aimed at international harmonization, PCT applications from Japan have been steadily rising[6], and proactive attempts have been made to acquire global rights.

F. Future issues and discussion

In 2014, patent law is going to be revised, and the extension of periods for procedure such as the payment of the patent fee will be provided more flexibly when an unavoidable reason (disasters) occurs to the applicant. Japanese system is thought to be very strict on periods for procedure compared to other major countries. Then, this revision is useful for international harmonization. Similar measures are going to be provided for the Utility Model Law, Design law, Trademark Law and international application law.

Moreover, the patent opposition system will be introduced, and anyone will be able to request for the opposition against patent rights during six months from the patenting. This revision is useful for appropriate protection of invention.

IV. TRANSITIONS IN THE EXAMINATION GUIDELINES AIMED AT CREATING AN INTELLECTUAL PROPERTY-BASED NATION - EXAMINATION GUIDELINES FOR PATENTS AND UTILITY MODELS -

The examination guidelines[7] used for patent examination are an important indicator of the advisability of granting rights and the breadth of the scope of rights. In light of the international harmonization of examination practices and developments in terms of judicial precedent, examination guidelines have been revised in recent years. Moreover, the Trilateral Offices of Japan, the USA, and Europe have conducted comparative studies of examination practices in relation to the requirements for novelty and inventive steps, as well as requirements for descriptions, etc., with all three countries playing a key role in deliberations aimed at international harmonization.

A. Requirements for Patentability (Novelty and Inventive Steps)

1) Transitions in the Revision of the Examination Guidelines

The requirements for novelty and inventive steps are

[6] Japan Patent Office, "Annual Report (FY2012)", June 2012, p.2

[7] Japan Patent Office, "Examination Guidelines for Patent and Utility Model in Japan" (revised March 2012)

explained in detail in the Examination Guidelines for Patent and Utility Models in Japan (hereinafter referred to as the Examination Guidelines) in "Part II Requirements for Patentability".

The December 2003 revision of the Examination Guidelines stipulated that in finding a claimed invention described in a publication, consideration should be given to common general knowledge at the time that the application concerned is filed, rather than at the time that the publication was distributed. This was because the revision of the PCT guidelines resulted in the International Searching Authority and International Preliminary Examining Authority being able to choose whether the common general knowledge for consideration when judging the disclosure of an invention described in a publication should be that current at the time the publication was distributed. or rather at the time that the application concerned is filed. As such, based on the stance taken in major judgments, Japan decided to take into account the common general knowledge current at the time that the application concerned is filed. This issue is a major point of contention in judgments concerning novelty and inventive steps, so international discussions will be required in the future with a view to international harmonization.

In the June 2006 revision of the Examination Guidelines, the approach to be taken in the event that the claim has a limitation of use was clarified, including in relation to the invention of uses. This revision prescribed that there would be cases in which the interpretation of claims would take place, including in relation to the limitation of use, but caution is required since the approaches to limitation of use do not necessarily correspond exactly in all three countries, as may be seen in the comparative studies of examination practices carried out by Japan, the USA, and Europe and described below.

2) Comparative Studies by the Trilateral Offices of Japan, the USA, and Europe

Comparative studies of examination practices regarding novelty have been carried out by the Trilateral Offices of Japan, the USA, and Europe, leading to the publication of the Comparative Study Report on Novelty (November 2009), as well as the publication of a study of hypothetical and real cases (November 2009). According to these reports, the practices of the Trilateral Offices correspond to each other in terms of the points based on which novelty can be denied – even in cases in which some of the matters in the claim are not disclosed in the cited documents – and it was demonstrated that there is no major difference in techniques for judging novelty. In three of the six examples in the case studies, however, the judgments of the Trilateral Offices differed, particularly in the case of items defined by their use, wherein "the respective examination guidelines and/or rulings decide whether or not a new use for a known item can confer novelty on the item in question" – suggesting a difference in approach between Japan, the USA, and Europe.

In Europe and the USA, even if the sole difference is in terms of use, inventions of items involving the limitation of use are not accepted as having novelty solely on the basis of a difference in use, as this is not a matter used to define an invention. In contrast, in Japan, as described above, the Examination Guidelines prescribe that there are cases in which the interpretation of claims will take place, including with regard to the limitation of use. In Europe, however, there is an exception in the case of the invention of uses for drugs, with novelty being accepted on the basis of their use, as stipulated in the revised European Patent Convention (known as EPC 2000)[8)]. Japanese and European practices regarding drug use are increasingly coming to resemble each other, with novelty being accepted regarding drug administration methods in Europe in recent years, for example, as an invention of drug use. There has also been a trial decision indicating that Swiss-type claims[9)] will no longer be accepted in the future (Enlarged Board of Appeal, decision G 2/08, 19 February 2010).

Descriptions of use limitations are used in a wide variety of fields, not only the drug field. Further discussions aimed at international harmonization in practices relating to the limitation of use are likely to be required, centered on Japan, the USA, and Europe.

Comparative studies of examination practices regarding inventive steps have been carried out by the Trilateral Offices of Japan, the USA, and Europe, leading to the publication of the Comparative Study Report on Inventive Step/Non-obviousness (June 2008), as well as the publication of a study of hypothetical and real cases (November 2008). As a result, it emerged that the Trilateral Offices have a common practice in terms of "certifying differences between the claimed invention and the cited invention, and judging whether a person with ordinary skill in the art could have devised the claimed invention, taking into account the state of the art." Opinions differed in one of the six cases, however, with the European and US authorities judging that there was no novelty, while the Japan authority judged that there was novelty but no inventive steps.

In terms of techniques for judging inventive steps, the "problem-and-solution approach" is adopted in Europe, which involves identifying the "objective technical problem" to be solved, after determining the closest prior art. In Japan and the USA, however, it is not necessary to define the objective problem to be solved. Moreover, since the KSR Supreme Court decision[10)] rulings on non-obviousness in the USA, "the question of whether or not an invention is obvious is evaluated after taking all facts into account, regardless of the specific motive for devising the claimed invention or the problem that a person with ordinary skill in the art was trying to solve." More specifically, the strict application of the TSM test, which involves demonstrating that teaching, suggestion,

8) EPC, Article 54 (4) & (5)

9) Claims taking the form "use of...", as in "Use of substance X in the manufacture of a medicament for the treatment of condition Y".

10) U.S. Supreme Court No. 04-1350 (April 30, 2007). KSR International v. Teleflex Inc.

or motivation led to the combination of elements in the prior art by a person with ordinary skill in the art, has been rejected by the Supreme Court, resulting in judgments regarding the obviousness of inventions being required to be more stringent than before. In Japan, on the other hand, in terms of probable cause or motivation in judgments regarding inventive steps, the Examination Guidelines stipulate the following: (1) relation of technical fields; (2) close similarity of problems to be solved; (3) commonality of working or functions; and (4) implications in the cited inventions. Further discussions aimed at international harmonization in techniques for judging inventive steps are likely to be required, centered on Japan, the USA, and Europe.

B. Requirements for Description, etc.

1) Transitions in the Revision of the Examination Guidelines

The requirements for descriptions and claims are explained in detail in the Examination Guidelines for Patent and Utility Models in Japan (hereinafter referred to as the Examination Guidelines), in "Part I Description and Claims".

In the October 2003 revision of the Examination Guidelines, the two types of violations of Article 36 (6) (i) (violation of the support requirement) of the Patent Act cited as types that do not correspond to an invention in expressive terms under the Examination Guidelines were supplemented by two further types cited as those that do not correspond to an invention in substantial terms. This revision was made with reference to the provisions of the PCT, and is one example of the international harmonization of the Examination Guidelines.

In the September 2011 revision of the Examination Guidelines, the basic approach to Article 36 (6) (i) (support requirement) and (ii) (clarity requirement), and Article 36 (4) (i) (enablement requirement) was maintained as it was. Additionally, the approach was clarified – and revisions made regarding inconsistencies between the requirements – in order to achieve greater consistency. In the future, it will be important to clarify the Examination Guidelines as required in order to make them more user-friendly.

In the June 2013 revision of the Examination Guidelines on Article 37, "the inventions that determined presence or absence of STF before STF is discovered" and "the inventions having the same or equivalent STF as first discovered STF" became the subject of the examination. Moreover, the inventions that it is effective to be examined together became the subject of the examination.

2) Comparative Studies by the Trilateral Offices of Japan, the USA, and Europe

Comparative studies of examination practices regarding the requirements for disclosure and claims have been carried out by the Trilateral Offices of Japan, the USA, and Europe, leading to the publication of the Comparative Study Report on Requirements for Disclosure and Claims (December 2007), as well as the publication of a study of hypothetical and real cases (June 2008). As a result, it was determined that their opinions corresponded in three of the six cases. However, whereas the Japanese authority ruled that there were shortcomings under the requirements for descriptions in two cases, the European and US authorities judged that the requirements were satisfied. Moreover, one case was an invention in the field of biotechnology, where all three authorities reached different conclusions from each other regarding adequacy in terms of the description requirements.

One of the cases that Japan judged to be inadequate, while Europe and the US judged the requirements to have been satisfied was an invention of a manufacturing method for polarizing film, wherein the manufacturing conditions were prescribed as mathematical formulas, and the description included two examples of performance of the manufacturing method and two comparative examples. In relation to this, whereas Japan required that "specific examples be disclosed to the extent that the desired effect can be achieved and be recognized by a person with ordinary skill in the art, insofar as they are within the scope designated by the mathematical formula", Europe's finding was that "The two examples of performance satisfy the conditions set out in the parameters, and there are also comparative examples. No further evidence necessary." In addition, the US response was "Applicant is not required to provide examples or explain why or how an invention works, provided that one of ordinary skill in the art would not have reason to question whether the invention can be made or used." This example shows that Japan operates stricter description requirements than Europe or the US.

If the operation of description requirements in Japan is stricter than in Europe or the US, something will need to be done from the perspective of the international harmonization of patent examination. As such, it is important for the Trilateral Offices to continue their deliberations aimed at the international harmonization of examination practices, by conducting case studies regarding description requirements.

V. TRANSITIONS IN EXAMINATION-RELATED SYSTEMS AIMED AT CREATING AN INTELLECTUAL PROPERTY-BASED NATION

One key issue in creating an intellectual property-based nation is the approach to patent examination. Expediting patent examination is a particularly pressing issue, so the Japan Patent Office has introduced various systems and measures relating to patent examination, endeavoring to ensure swift examination. Expediting patent examination is meaningless in policy terms, however, if the quality of examination declines as a result. Accordingly, while seeking to expedite patent examination, the Japan Patent Office has been promoting systems and measures aimed at maintaining and enhancing the quality of patent examination, as well as seeking to implement quality control in this area.

A. Initiatives Aimed at Expediting Patent Examination

1) The Accelerated Examination System

The accelerated examination system is an initiative aimed at expediting patent examination. Launched in February 1986, this system involves bringing forward [11)] patent examinations if the applicant submits a request in this regard. In terms of the requirements for accelerated examination, the system initially focused solely on applications relating to the working of inventions (applications relating to inventions that were already being worked, or were due to be worked within two years), but the system was subsequently expanded amid growing need for an accelerated examination system. In January 1996, the scope was extended to include applications filed in other countries (applications relating to inventions for which applications had also been filed overseas), with applications from SMEs and venture companies, universities and TLO, and with public research institutions added in July 2000. More recently, green technology-related applications (applications focused on environment-related technology) were added in November 2009, while applications relating to support for the recovery from the earthquake disaster (applications from companies and individuals affected by the Great East Japan Earthquake) were added in August 2011. Even now, the number of applications for accelerated examination is on the rise, with 12,157 applications received in 2011[12)]. The need for the accelerated examination system remains high, so it will probably be beneficial to consider expanding the scope of eligibility for accelerated examination further in the future, as necessary.

Moreover, the super accelerated examination system was launched in October 2008. Focusing on applications eligible for normal accelerated examination that are deemed to be of greater importance, which fall into the category of applications relating to the working of inventions or applications filed in other countries, this system offers even faster [13)] examination than under the normal accelerated examination system. In the future, it will likely be important to reinforce the competitiveness of companies by promoting efforts to expedite patent examination, and eventually aiming to achieve real-time examination (examination with no waiting period).

2) The Patent Prosecution Highway (PPH)

The Patent Prosecution Highway (PPH) was launched (entered into force) between Japan and the USA in July 2006. The PPH is a system for use in the event that patent applications regarding a single invention are submitted in multiple countries, and allows the results of the examination in the first country to be used in other countries – thereby making it possible for examination in those countries to begin sooner. This kind of international work-sharing in patent examination had been discussed at meetings of the Trilateral Offices of Japan, the USA, and Europe for many years before the PPH was launched. At the trilateral meetings, discussions originally began with the sharing of information about search tools and the exchange of search results, and the realization of the PPH was achieved amid efforts to promote harmonization of examination practices, with a view to approving each other's patent examinations. The success of the PPH has been underpinned by many years of effort by the Trilateral Offices.

The focus of the PPH has expanded since its launch in July 2006, and as of the end of January 2013, Japan implements it in relation to 24 countries and regions[14)]. Further expansion of the countries eligible for the PPH is being considered, and it is anticipated that this will promote global patent acquisition. The quality of the examination results in the first country is crucial, however, in order to ensure that countries can benefit from the advantages of the PPH. In the future, as well as scrutinizing the quality of patent examination in countries eligible for the PPH, negotiations about expanding its scope should be undertaken after adequate verification of the quality of patent examination in the counterpart country concerned.

Moreover, the first Plurilateral Patent Prosecution Highway Working-Level Meeting was held in February 2009, with participants considering how to enhance the usability of the PPH. As a result, the PCT-PPH pilot program was launched on January 29, 2010, enabling accelerated examination based on a simplified procedure to be offered at the PCT national stage. Moreover, on July 15, 2011, the PPH MOTTAINAI pilot program [15] was launched, making it possible to submit PPH requests based on an examination by any participating country finding that an invention is patentable, irrespective of the country in which the patent application was first filed. It will be important to continue to conduct deliberations aimed at further enhancing the usability of the PPH in the future.

JP-FIRST was launched in FY2008 as an initiative that seeks to promote the prompt acquisition of patents through a process in which patent applications from Japan that are filed in other countries as well as in Japan first undergo accelerated examination within Japan, with the results then used by the foreign patent offices concerned[16)]. Just like the PPH, this system is expected to promote the global acquisition of patents.

[11)] In 2011, the average waiting period for examination of applications under the accelerated examination system was about two months from the time of requesting accelerated examination.

[12)] Japan Patent Office, "Annual Report (FY2012)", June 2012, p.131

[13)] Under the super accelerated examination system, the time from requesting such examination until the first action is issued is no more than one month, with subsequent examination also being conducted within a month of the submission of the written opinion/amendment.

[14)] Japan Patent Office, "Patent Prosecution Highway" (Japan Patent Office website) (updated January 30, 2013) http://www.jpo.go.jp/cgi/link.cgi?url=/torikumi/t_torikumi/patent_highway.htm (accessed January 30, 2013)

[15)] Implemented in eight countries: Japan, the USA, the UK, Canada, Australia, Finland, Russia, and Spain.

[16)] Japan Patent Office, "Annual Report (FY2012)", June 2012, p.141

3) Upgrading of Systems within the Japan Patent Office

One way in which systems within the Japan Patent Office are being upgraded with the aim of expediting patent examinations is through the outsourcing of prior art document searches (search outsourcing). Over the last decade, there has been a major shift away from delivery-style outsourcing (search outsourcing that involves only the submission of search results in the form of a report) and toward dialogue-style outsourcing (search outsourcing in which the external searcher explains the search results face-to-face with the examiner) – thereby increasing the effectiveness of search outsourcing[17].

Moreover, as a result of the revision of the Act on Special Provisions[18], the requirement to outsource prior art document searches to public interest corporations was abolished in 2004, making it possible to utilize the dynamism of the private sector. As a result, the number of registered search organizations conducting prior art document searches stood at nine as of April 1, 2012[19]. Thus, efforts to enhance and achieve greater efficiency in the system of prior art searches at the pre-examination stage have reduced the waiting time before examinations commence.

The hiring of fixed-term examiners, which began in FY2004, is another key measure that is enhancing systems within the Japan Patent Office with a view toward expediting patent examination. Fixed-term examiners are officials with a fixed term of office who are hired as patent examiners for a period of five years (re-hiring enables them to be employed for a maximum of ten years) in accordance with the Act on Special Measures of Employment and Remuneration of Officials with Fixed Term of Office in the Regular Service (Act on Officials with Fixed Term of Office). By hiring about 100 fixed-term examiners for a period of five years every year beginning in FY2004, the number of examiners has been boosted by about 500, which has contributed to expediting patent examination. In March 2013, Japan Patent Office explained the new policy to shorten "a period to obtaining a right" and "a period to obtaining first office action" within 14 months and 10 months respectively by 2023.

Thus, efforts have been made to increase the speed of patent examination not only through legal system reforms, but also via the promotion of systems relating to examination.

B. Initiatives Aimed at Improving the Quality of Patent Examination

1) The Interview Examination System

The system of interview examinations was introduced with the aim of helping to make examination procedures more efficient by promoting smooth communication between examiners and applicants or their attorneys[20]. Interview examinations enable applicants and others to explain such matters as the details of the technology or technological trends to the examiner – thereby contributing to more accurate examinations, as well as allowing the examiner's opinion regarding an Office Action, etc. to be confirmed face-to-face – and facilitating a more appropriate response by the applicant/attorney thereafter. Consequently, it is one system that is effective in improving the quality of patent examinations.

In terms of the format of the interviews, examiners visit interview venues nationwide to conduct regional interview examinations where they meet with the applicant face-to-face. In addition, a system of video-based interview examinations has been introduced through the installation of video-conferencing systems in patent offices in each region. These forms of interviews are effective in increasing the convenience of interview examinations.

Interview examinations are actively implemented in accordance with the Interview Guidelines formulated in July 1995. The Interview Guidelines were revised in October 2007, with the objective of making communication between examiners and attorneys, etc. smoother – thereby contributing to swifter, more precise examinations. More specifically, the revisions sought to clarify the requirements for corresponding persons on the applicant's side, as well as setting out the approaches to interviews between examiners and attorneys, etc. and communication by telephone or facsimile instead of interviews[21].

Interview examinations are conducted face-to-face between the examiner and the applicant, so the procedures and responses required differ from those used for normal document-based examinations. In the future, it will continue to be important to gain a precise understanding of the needs of applicants in terms of approaches to interview examinations, and to revise the Interview Guidelines as required.

2) The Information Submission System

The information submission system[22] involves accepting statements containing information that is useful in conducting an examination, such as the fact that an invention relating to a patent application involves no novelty or inventive steps, or that it does not satisfy the requirements for the description. 6,538 submissions of information were received in 2011[23].

There are many cases in which the information provided via the information submission system is useful in substantive examinations, and its effective use by examiners has contributed to improving the quality of examinations. In addition, it is vital for the person submitting information to be able to ascertain the examination status, including such matters as how long they have to submit information to ensure that it is provided in time for the start of the patent

[17] The number of cases of dialogue-style outsourcing rose from 130,000 in 2004 to 214,000 in 2011.
[18] Act on Special Provisions for Procedures related to Industrial Property Right
[19] Japan Patent Office, "Annual Report (FY2012)", June 2012, p.129-130
[20] 4,636 interview examinations were carried out in 2011.
[21] Japan Patent Office, "Interview Guidelines" (revised October 2007)
[22] Order for Enforcement of the Patent Act, Article 13-2
[23] Japan Patent Office, "Annual Report (FY2012)", June 2012, p.133

examination, as well as whether it can be used in a substantive examination by an examiner. Accordingly, rough indicators of the timing of the examination of applications have recently begun to be published on the website of the Japan Patent Office via its Patent Examination Timing Inquiry Service[24]. This has been beneficial in facilitating the effective use of the information submission system.

Moreover, when the opposition system was abolished in 2002, the post-grant information submission system[25] was introduced to replace it. This system also involves the submission of useful information, such as the fact that an invention relating to a patent application involves no novelty or inventive steps, or that it does not satisfy the requirements for the description. In the case of post-grant information submission, however, the information can only be used effectively in the event of a trial. In this sense, the post-grant information submission system does not adequately fulfill the role played by the opposition system. This problem is likely to be eliminated in the future, with the introduction of a post grant review system.

3) Upgrading of Systems within the Japan Patent Office

Examiner consultations have also been introduced to upgrade systems within the Japan Patent Office, with a view to improving the quality of patent examination. Under normal circumstances, one examiner handles one patent examination, but some specific applications (consultation cases) are handled on the basis of consultation among multiple examiners (examiner consultations). The cases subject to consultation are important cases, or those in which it is difficult to reach a judgment regarding their patentability – but individual examination offices sometimes decide to adopt the examiner consultation approach through their own initiative. The number of examiner consultations has been on the rise in recent years, and they are being used effectively in order to improve the quality of patent examinations. Examiner consultations were carried out for around 60,000 applications in FY2011.

In April 2007, the Quality Audit Office was established within the Japan Patent Office, creating a new system aimed at improving the quality of examinations. In partnership with the Examination Standards Office, the Quality Audit Office regularly exchanges opinions with users, providing them with an outline of initiatives aimed at maintaining and enhancing the quality of examinations, as well as seeking information about their opinions and requirements regarding patent examinations. The information gained through such exchange of opinions is useful in conducting quality control of patent examinations by examination offices, as well as being utilized in deliberations aimed at putting in place additional quality control systems[26].

As described above, the Japan Patent Office has been endeavoring to provide precise protection for intellectual property by pursuing not only speed, but also enhancements in the quality of patent examinations. It will be important to maintain a balance between both aspects in the future.

VI. TRANSITIONS IN LEGAL SYSTEM REFORMS IN OTHER COUNTRIES

A. International Harmonization of Intellectual Property Legislation in the USA

Pro-patent policy has been promoted in the USA since the 1980s. More recently, President Obama was instrumental in formulating the Strategy for American Innovation in 2009, which cited the necessity of protecting intellectual property in overseas markets, among other recommendations. Subsequently, the United States Patent Act was revised in September 2011, resulting in the creation of the Leahy-Smith America Invents Act. The objectives of the first major revision in 60 years included improving the quality of patents, reducing the cost of litigation, and promoting international harmonization, so the revisions covered a wide range of areas. The US patent system in place hitherto included some systems peculiar to the USA, such as the first-to-invent principle and linguistic discrimination in relation to excluding later applications (the so-called Hilmer doctrine problem), but this revision of the Patent Act resulted in substantial reforms of the system, including a shift to the first-to-file principle, the abolition of the Hilmer doctrine, and the introduction of post grant reviews.

Various problems have been pointed out in regard to the first-to-invent principle, such as the fact that it imposes a considerable burden on the applicant, including the necessity of a response that takes into consideration certification of the date of the invention, as well as the fact that rights lack stability. As such, the shift to the first-to-file principle implemented under this revision of the Patent Act resolves these issues, and also has substantial advantages for Japanese companies. However, the grace period prescribed under the United States Patent Act differs from those employed in Japan and Europe: Even if a third party has disclosed an identical invention to one's own before one has filed a patent application, one's own application will not be affected by the disclosure by the third party as long as their invention was disclosed after one disclosed one's own invention (the so-called "first-to-publish principle"). Accordingly, caution is required with regard to the fact that the US patent system is not fully based on the first-to-file principle, and it will be necessary for Japan to continue negotiations with the USA regarding this and other unresolved problems with a view toward the international harmonization of patent systems.

[24] Japan Patent Office, "Patent Examination Timing Inquiry Service" (Japan Patent Office website) (updated January 28, 2013) http://www.jpo.go.jp/torikumi/t_torikumi/search_top.htm (accessed January 30, 2013)

[25] Order for Enforcement of the Patent Act, Article 13-3

[26] Japan Patent Office, "Annual Report (FY2012)", June 2012, p.135-136 (2012)

B. The Regional Intellectual Property System in Europe

In Europe, patent applications and examinations are conducted in an integrated fashion by the European Patent Office (EPO), in accordance with the European Patent Convention (EPC). The EPC was revised on December 13, 2007 and the revised European Patent Convention (EPC 2000) entered into force. This revision introduced many procedural improvements compared with the pre-revision EPC (EPC 1973), increasing convenience for both applicants and holders of patent rights.

In order to make patent rights valid in each country once the decision of patent grant has been issued, it is necessary in Europe as a general rule to translate the claim and description into the language of each country. Moreover, when exercising patent rights, litigation must be pursued in each individual country. Accordingly, a system of patents with unitary effect and an integrated patent litigation system has been proposed in order to alleviate the burden on applicants in terms of translation and litigation costs, as well as to ensure that court proceedings regarding infringements or validity after patent rights have been granted can be carried out in an integrated fashion.

The introduction of the system of patents with unitary effect and the integrated patent litigation system has the aforementioned advantages for applicants, but many of the details of the legal system reforms that will be required are yet to be finalized. Japan's cooperation and support are currently being sought, and close attention will need to be paid to developments in terms of legal system reforms in Europe in order to ascertain what kind of legal system Europe is aiming to introduce.

C. Regional Integration in the Asia-Pacific Region

In 1994, APEC[27] adopted the Bogor Goals, which aimed to achieve free and open trade and investment in the Asia-Pacific region by 2010 for industrialized economies, and by 2020 for developing economies. In terms of cooperation by Japan in the intellectual property field, the APEC Cooperation Initiative on Patent Acquisition Procedures proposed by Japan in 2007 has been approved, marking the beginning of this initiative aimed at streamlining application procedures, promoting intra-regional cooperation in patent examination, and enhancing patent examination capabilities within the APEC region. More recently, Japan proposed the Initiative to Promote Membership of Treaties on Intellectual Property Rights, with the objective of encouraging membership of various treaties on intellectual property (e.g. the Hague Agreement and the Madrid Protocol). Such initiatives by Japan seek to promote the upgrading of intellectual property legislation within the APEC region, and they would appear to be beneficial for Japanese companies seeking to expand within that region.

With regard to ASEAN[28], the establishment of an ASEAN Community was agreed in 2003. ASEAN member states subsequently signed the Cebu Declaration (2007), in which they declared that they would expedite the establishment of the ASEAN Community so that it could begin in 2015. Some progress has been seen in the intellectual property field, such as the 2011 formulation of the ASEAN Intellectual Property Rights Action Plan 2011-2015, which stipulated that the results of patent examinations should be shared with other countries within the region. ASEAN is one of the world's foremost growth markets, so it has a solid economic relationship with Japan. It will continue to be vital to promote further efforts to enhance the intellectual property system in ASEAN, with a view to strengthening the international competitiveness of Japanese companies. In addition, promoting membership of intellectual property treaties (e.g. the Hague Agreement and the Madrid Protocol), undertaking human resource development (inviting practitioners to participate in training concerning intellectual property in Japan), and improving awareness of intellectual property rights (through local seminars, etc.) will likely be beneficial in terms of cooperation on the part of Japan.

As part of the Trans-Pacific Partnership (TPP), negotiations are taking place with the participation of the USA regarding a broad regional economic partnership agreement aimed at economic liberalization in the Asia-Pacific region. One of the realms of negotiation in TPP is the intellectual property field, and stipulations are being considered regarding such matters as adequate and effective protection of intellectual property, as well as law enforcement focused on counterfeit goods and pirate copies. Such efforts to strengthen the protection of intellectual property will be beneficial to Japanese companies in seeking to do business within the TPP region. The countries participating in TPP negotiations include some that have free trade agreements (FTA) with the USA which include, provisions that are not consistent with Japan's legal system, however, such as the provision applying the exception to lack of novelty to applications submitted within 12 months of publication by the inventor. As such, Japan will need to adopt a cautious response when such provisions are discussed in TPP negotiations.

Thus, various forms of regional integration are being promoted in the Asia-Pacific region, and efforts are being made to harmonize systems relating to intellectual property legislation within the respective regions. In terms of Japan's

(Reference Literature)
1. Japan Patent Office, "Clause-by-Clause Commentary on Industrial Property Laws (19th Edition)", Japan Institute of Invention and Innovation, 2012
2. Intellectual Property Strategy Headquarters, "Intellectual Property Strategic Programs 2003 - 2012"

[27]) Asia-Pacific Economic Cooperation (APEC)
[28]) Association of Southeast Asian Nations (ASEAN)

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approach to international cooperation, should we support the intra-regional harmonization of systems, or would it be better to support worldwide international harmonization? Once upon a time, it seemed that various regional systems were on track toward global harmonization, and that they would follow the same path, but one wonders whether this is indeed the case today? In the future, Japan's approach to international cooperation should be examined after giving sufficient consideration to the direction being taken by each region in its intellectual property legislation.

VII. COMPARATIVE STUDY

Japan has been advancing several intellectual property policies as pro-patent policies for past ten years, as explained above. However, in other countries, there are some trends against pro-patent policies.

In this chapter, two cases (India and U.S.A.) are focused as trends against pro-patent policies, and discussed as comparative study.

In the future, Japan should internationally advance pro-patent policies in consideration of those trends against pro-patent policies.

A. Case Study -1 (Glivec case)

- Indian Supreme Court Decision of Patentable Subject Matter of Medicines -

On April 1, 2013, the Indian Supreme Court judged that a patent should not be granted to the patent application for the medicine "Glivec," which is used to treat chronic myelocytic leukemia, etc. This application was refused under Article 3(d) of the Patent Act of India based on the (pre-grant) opposition filed in January 2006. Since the appeal against the decision of refusal was also refused by the Intellectual Property Appellate Board (IPAB) in June 2009, the final appeal was filed with the Supreme Court. This case had been brought before the Madras (Chennai) High Court in August 2007 as a dispute over the conformity of Article 3(d) of the Indian Patent Act with the TRIPS Agreement and with Article 14 of the Indian Constitution. The High Court held that Article 3(d) of the Indian Patent Act is in conformity with Article 14 of the Indian Constitution. Regarding this point, this case was finalized without appealing to the Supreme Court. The High Court did not examine the conformity with the TRIPS Agreement by holding that the High Court does not have jurisdiction over this issue.

In the Glivec case, the supreme organ of the Indian judicial system presented, for the first time, its interpretation of Article 3(d) of the Indian Patent Act, which imposes certain restrictions on the grant of a patent for a medicine. This is why the Glivec case attracted great international attention.

1) Provision concerning patentability (Article 3(d) of the Indian Patent Act)

Article 3 of the Indian Patent Act is the provision that specifies unpatentable inventions (what are not inventions). In particular, Article 3(d) specifies that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance" and defines it as what are not inventions. Such provision is considered to be aiming to prevent "evergreening," which is a practice unique in the pharmaceutical industry.

"Article 3: What are not inventions (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation; For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

2) Determination of the court of prior instance (Madras High Court, Intellectual Property Appellate Board (IPAB))

While the purpose of filing this case with the Madras (Chennai) High Court was to seek rescission of the decision of examiner's refusal, the point at issue at the High Court was the conformity of Article 3(d) of the Indian Patent Act with the TRIPS Agreement and Article 14 of the Indian Constitution.

With regard to the conformity with the TRIPS Agreement, the plaintiff asserted that Article 3(d) of the Indian Patent Act violates Article 27 of TRIPS, which specifies that a patent shall be granted for an invention in any technical field. Regarding this point, the Court dismissed the plaintiff's claim by holding that the TRIPS Agreement is an international treaty and not a domestic law of India and therefore that no Indian High Court has jurisdiction over this issue.

Regarding the plaintiff's assertion concerning the conformity with Article 14 of the Indian Constitution, the Court held that the phrase "enhancement of the known efficacy" specified in Article 3(d) of the Patent Act is unclear and violates the "equality before the law" guaranteed under Article 14 of the Indian Constitution on the grounds that such unclear provision could allow the Patent Controller to exercise his authority at his own discretion. However, in order to determine whether equality before the law has been achieved or not, "uncontrolled discretion" is necessary. The court dismissed the plaintiff's claim by holding that the mere risk of the Patent Controller's abuse of his authority would not constitute violation of the Constitution.

The appeal against the examiner's decision of refusal was subsequently subject to the jurisdiction of the Intellectual Property Appellate Board (IPAB), which conducted further examination. In June 2009, the appeal was refused once again

under Article 3(d) of the Indian Patent Act.

3) Determination of the Supreme Court

The invention claimed in the patent application that was disputed in this case was "imatinib mesylate β crystalline form," which is an invention created by transforming the publicly-known imatinib mesylate, which is a substance with a tumor-inhibitory effect, into the form of β crystalline so that the invention has an advantage in terms of fluidity, thermodynamic stability and hygroscopicity. This invention may be used for medical purposes such as the treatment of chronic myelocytic leukemia. The prior document disclosed "imatinib mesylate" with its effects (such as a tumor-inhibitory effect).

In the judgment, regarding the interpretation of Article 3(d) of the Indian Patent Act, the Court held that, in the case of a medicine to treat a disease, the "efficacy" should be interpreted solely as "the effect of treatment" and subject to strict, rigid judgment criteria. Moreover, the court held that "efficacy" should not be interpreted as any kind of advantageous or beneficial properties, but as something directly related to "the effect of treatment." Regarding the "enhancement of the known efficacy," the court held that, even if any form specified in the section "Explanation" acquires any property that is inherently present therein, such as "resolvability" in the case of salt and "hygroscopicity" in the case of polymorphs, it would not constitute "enhancement of the known efficacy."

In this court case, the court found that the physicochemical properties claimed in the patent application, namely, more beneficial flow properties, better thermodynamic stability and lower hygroscopicity, may not be subject to Article 3(d) of the Indian Patent Act on the grounds that Article 3(d) applies only to the properties that are directly related to the "effect of treatment." The Court also found that, while the significance of "bioavailability" in enhancing the effect of treatment must be asserted and proved based on research data in each case where such enhancement is claimed, neither assertion nor proof was presented in this case. Furthermore, the court held that "safety" and "toxicity" are not the points of dispute in this case and therefore that the court does not judge whether they may be regarded as the "effect of treatment."

4) Influence of this court case

Having received this judgment, the Indian corporation Novartis expressed their policy of not making any further investment in R&D activities in India. The judgment was a hard hit to Novartis, which had successfully obtained patent protection in many other countries. This court case prompted developed countries' reactions. For instance, the Pharmaceutical Research and Manufacturers of America stated that this judgment is an example that indicated the deterioration of the innovation environment in India.

In contrast, generic drug makers in India welcomed this judgment. Also, “Medecins Sans Frontiers” supported the Supreme Court Judgment by considering it as a victory for patients' access to medicines in developing countries.

B. Case Study -2 (Myriad case)

- US Supreme Court Decision of Patentable Subject Matter of Gene -

On June 13, 2013, the Supreme Court of the United States issued a ruling against gene patents. In this case, the point of contention was the validity of patents held by the US pharmaceutical company Myriad Genetics, Inc. (Myriad) with regard to genes associated with the onset of breast and ovarian cancers (BRCA1 and BRCA2). The ruling stated that genes themselves are a product of nature and not something created artificially, so they are not patent-eligible; but that synthetic DNA is patent-eligible since it is artificially created rather than naturally occurring. The term "patent eligible" here refers to the basic question of whether or not something should be eligible for protection by a patent in the first place, with judgments based on the premise of requirements for patent eligibility such as novelty and inventive steps. In Japan, this is judged on the basis of eligibility as an invention under the Patent Act (Article 2 (1) of the Patent Act).

1) Background to the case: Quashing and remand of the Court of Appeals ruling

The history of this case begins with the ruling by the District Court for the Southern District of New York against the validity of Myriad's gene patents (BRCA1 and BRCA2). Having found that both genes were related to the onset of breast and ovarian cancers, Myriad identified their position on the genome and decoded the base sequences.

The Court of Appeals for the Federal Circuit (CAFC) subsequently overturned the District Court's ruling, and accepted the validity of the gene patents. The Supreme Court quashed the ruling by the Court of Appeals on March 26, 2012, however, and remanded the case back to the CAFC to be reheard in light of the Prometheus ruling.

The Prometheus ruling was a Supreme Court ruling (March 20, 2012) against the validity of patents held by Prometheus Laboratories, Inc., in which the Supreme Court quashed the CAFC ruling and remanded the case back to the CAFC – rejecting the validity of the Prometheus patents. The Prometheus patents involved inventions relating to methods of drug administration. In ruling the patents to be invalid, however, the Supreme Court stated that the reason was that the discovery of natural laws is a basic tool of science and technology, and that granting patents for such discoveries could impede the use of natural laws – thereby running the risk of inhibiting future innovation.

The Myriad patents included the invention of genes, so if those genes were held to be "the discovery of a natural law" in light of the Prometheus ruling, it would mean that the gene patents were invalid, which would substantially change the operation of the patent system, wherein patents had conventionally been granted for genes.

Given this situation, and amid considerable attention from

the pharmaceuticals sector, the CAFC again issued a judgment in August 2012 recognizing the validity of Myriad's gene patents.

More specifically, noting that all things are derived from nature and are consistent with laws of nature, the opinion stated that the genes in this case were not products of nature, and that although they were consistent with laws of nature, they had been created by human hand.

Subsequently, this case was heard again by the Supreme Court – and the second ruling in this case became the focus of attention.

2) Supreme Court decision: Naturally occurring genes not patent-eligible

On June 13, 2013, the Supreme Court issued its second ruling, once again rejecting the validity of Myriad's gene patents (BRCA1 and BRCA2). The ruling stated that these genes themselves were products of nature that were in existence before their discovery by Myriad, rather than being something created by that company – meaning that they did not meet the criteria for being patent eligible. It stated, however, that synthetic DNA is patent-eligible because it is artificially created rather than naturally occurring.

In addition, the ruling did not specify which of the claims in Myriad's patents were patent-eligible and which were not.

According to this Supreme Court ruling, genes that exist in nature are not patent-eligible in principle. Under normal circumstances, isolating genes from their natural state involves severing the ends of those genes and carrying out a degree of DNA manipulation (replenishing bases, etc.). In that sense, therefore, one can take the view that they differ from naturally occurring genes. From the perspective of the Supreme Court ruling, however, the fact of their isolation alone does not render them patent-eligible.

According to the Supreme Court, on the other hand, synthetic DNA is artificially created rather than naturally-occurring, making it eligible for a patent. Complementary DNA (cDNA) is patent eligible, for example, because it has been synthesized from naturally-occurring genes via processes including the removal of intron sequences.

While the Supreme Court ruling therefore rejects the validity of gene patents, caution is required with regard to the fact that it does not rule against all gene patents.

3) Impact of the Supreme Court ruling: Need to have enhanced a gene

Genomic DNA (gDNA) such as that involved in Myriad's patents in this case has hitherto been deemed eligible for the grant of a patent – but will no longer be patent eligible since it consists of naturally occurring genes.

Consequently, for inventions involving gDNA to be patent eligible, it will likely be necessary to enhance the gene in some way, using genetic engineering techniques. However, the majority of gene patents involve synthetic DNA (particularly cDNA), so one can take the view that the recent Supreme Court ruling will not have that great an impact.

It should be noted that, in the case of genes derived from prokaryotes (for example, Escherichia coli), the genes do not contain intron in the first place, so such cDNA has exactly the same base sequence as the naturally occurring genes. Consequently, caution is required, due to the possibility that genes derived from prokaryotes might not be patent eligible, even in the form of cDNA.

Outside the genetic field, some inventions of microorganisms or chemical substances such as proteins, for example, are identical to the naturally occurring version, but the filing of patent applications for these has been going on for some time and patents have been granted for them.

The recent Supreme Court ruling does not relate to any field other than genes, but caution will be required regarding trends in practice in the USA in future.

In Japan, "things that are mere discoveries and not creations" do not constitute inventions under the Patent Act, so patents are not granted in such cases.

The Examination Guidelines for Patent and Utility Models in Japan state that "mere discoveries, such as those of natural things such as ore or natural phenomena, for which an inventor does not consciously create any technical idea, are not considered to be a statutory invention," but that "if things in nature such as chemical substances or microorganisms have been artificially isolated from their surroundings, they are therefore creations and considered to be statutory inventions." In the future, caution will be required concerning differences in practice between Japan and the USA.

4) Discussion and observations: Issue is exploitation, not validity

One article highlighting the necessity of the intellectual property system is the 1968 The Tragedy of the Commons (Hardin, Science, Vol. 162, no. 3859), which suggests the possibility that inadequate protection of intellectual property could give rise to a wretched society (tragedy). Subsequently, the Tragedy of the Anticommons (Heller & Eisenberg, Science, Vol. 280, no. 5364) was published in 1998 as a counterpoint to this argument. In this article, the authors argue that the acquisition and management of intellectual property in the pharmaceutical field had gained momentum – eliminating the tragedy of the commons – and pointed out that the acquisition of rights to (patenting of) the outcomes of upstream basic research had escalated, thereby leading to problems in the form of the tragedy of the anticommons wherein downstream applied research was being stifled. The recent Supreme Court ruling could certainly be viewed as a prescription to cure the tragedy of the anticommons.

I would like to stress the fact, however, that the outcomes of upstream basic research are prerequisites for applied research. Weakening upstream patent protection could well reduce incentives for basic research, resulting in the decline of applied research – and thereby diminishing the possibility of saving lives through groundbreaking new drugs and inviting the return of the tragedy of the commons.

In the USA, Hollywood actress Angelina Jolie recently underwent a mastectomy after genetic testing revealed the presence of genes that indicated a high probability of developing breast cancer. As a result, interest in genetic testing for breast cancer is growing.

People in the medical community forecast that fees for breast cancer genetic testing will fall as a result of the recent Supreme Court ruling. if there had been insufficient incentive to pursue genetic research due to genes not being patent eligible, however, genetic testing for breast cancer might not have existed in the first place – and Angelina Jolie might have faced an even more unfortunate situation.

Rather than the validity of gene patents, then, I believe that the problem lies in methods of exploiting such patents. In the Supreme Court ruling in the Prometheus case, the existence of patents as a basic tool was debated in terms of the risk that they might inhibit future innovation. However, we must not lose sight of the fact that methods of exploiting patents could actually bring about this type of risk.

I would suggest that while using gene patents to maintain incentives to conduct future basic research, consideration should be given to policies for promoting the effective exploitation of patents by encouraging licensing activities focused on basic patents that are highly beneficial to the public – or providing government support in this regard. Then, the tragedy of the anticommons will change into the comedy of anticommons.

VIII. CONCLUSION

Ten years have passed since the Intellectual Property Basic Act entered into force. Over the last decade, legal system reforms in the intellectual property field have been promoted at a hitherto-unprecedented pace, and it is likely that the resultant achievements will form their own chapter in the history of intellectual property legislation. One hopes that further substantial legal system reforms will be implemented over the next ten years, without going against the tide of the reforms undertaken to date, and that efforts will be made to strengthen competitiveness and promote international harmonization.

Rather than simply introducing new laws and revising existing ones, the best way of increasing the effectiveness of legal system reforms will be to ensure that these are accompanied by relevant examination guidelines and systems relating to examination. As well as legal system reforms, it will be vital to promote the upgrading of various related measures, with the objective of creating an intellectual property-based nation from a variety of perspectives.

Japan has been advancing several intellectual property policies as pro-patent policies for past ten years, as explained here. However, in other countries, there are some trends against pro-patent policies. In this paper, two cases (India and U.S.A.) are focused as trends against pro-patent policies, and discussed as comparative study. In the future, Japan should internationally advance pro-patent policies in consideration of those trends against pro-patent policies in some countries.