# 21 How to Control the Quality of Patent Using Nonobviousness Requirement<sup>(\*)</sup>

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The inventive step requirement (non-obviousness requirement) is the most important requirement that decides the quality of a patent. This report is intended to draw suggestions for Japanese law through an overview of discussions on the non-obviousness requirement in the United States from the perspective of control of the quality of patents. This report considers discussions on the non-obviousness requirement in a multifaceted manner from two perspectives, that is, discussions on substantive determination standards and discussions on the development of a procedural system. With regard to substantive determinations, determination of non-obviousness in the United States has been changing since a recent Supreme Court judgment, and has been coming close to Japan where the Intellectual Property High Court has recently been changing the trends of determination of inventive step. In terms of procedures, the United States is making efforts to ensure the quality of patents while meeting various needs by preparing various systems through legal revisions while Japan adopts a policy of bringing problems under control by preparing an all-round trial for invalidation system. There is a significant difference in procedures between Japan and the United States. It should be noted that both of them have respective advantages and disadvantages.

#### I Introduction

#### 1 Awareness of Problems in This Report

The subjects of study in this report are the inventive step requirement (non-obviousness requirement) among the requirements for patentability as well as organizations and procedures by which fulfillment of the requirement is determined.

This report sets the perspective of "control of the quality of patents" for consideration. In this report, the term, "quality" of a patent, is used to indicate the quality which an invention should have by fulfilling the requirements for patentability or to straightforwardly indicate the fact that a patent fulfills the requirements for patentability.<sup>1</sup>

This report covers recent discussions on the inventive step requirement (non-obviousness requirement) in the United States in order to seek appropriate control of the quality of patents in the sense as mentioned above. Thereby, this report reveals suggestions obtained concerning the legal system of Japan. The United States is made subject to consideration because many discussions have been accumulated there and there seem to be many points that should be

amply used as reference for Japan.

#### 2 Crisis of Patents and Quality of Patents in the United States

#### (1) FTC and NSF Reports (2003 and 2004)

The revision to the U.S. patent law in 2011 (hereinafter referred to as "AIA" or the "2011 Revision") can be regarded as the United States' singular answer to a sense of crisis, that is, a crisis of patents. Discussions that led to the answer started with the FTC (Federal Trade Commission) Report<sup>2</sup> issued in 2003 and the NSF (National Science Foundation) Report<sup>3</sup> issued in 2004.

The NSF Report and the FTC Report have much in common. Both of them pointed out problems brought about by a decrease in the quality of patents and suggested tightening of substantive standards for granting patents and strengthening of procedures for checking the standards as measures for improvement. Concerns about the quality of patents and the necessity of promoting improvement of the quality from both substantive and procedural perspectives had been commonly recognized in the United States.

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# (2) Lawmaking and Judicial Movements toward Improvement of the Patent System

Movements to revise patent law began in response to the aforementioned two reports. However, the fact emerged that the semiconductor/software industries and the chemical/pharmaceutical industries have different interests in patents, and lawmaking made little progress.

On the other hand, the judiciary showed movements to reform the patent system. The eBay decision<sup>4</sup> in 2006 put a certain brake on problems, such as abuse of injunction by a right holder who does not work a relevant patent in relation to a software patent, etc., and a series of judgments of the Court of Appeals for the *Federal Circuit* (CAFC) put restraints on the amount of damages.<sup>5</sup> In addition, the Supreme Court tightened standards for obviousness through the KSR decision. <sup>6</sup> Therefore, the problem of the quality of patents is expected to be significantly improved at least in terms of the substantive aspect.

After that, the patent reform bill was finally passed and enacted in 2011. The most distinct characteristic of the Patent Reform Act of 2011 (AIA) is a shift to the first-to-file system from the conventional first-to-invent system. <sup>7</sup> Another distinct characteristic is the significant development of a mechanism for ensuring the quality of patents through expansion of procedures for disputing over the validity of a patent at the USPTO. A mechanism to ensure the quality of patents through procedures at the USPTO was established.

#### (3) Discussions on the Crisis of Patents

The academy has also developed various discussions amid the progress of discussions on the reform of the patent system as mentioned above

James Bessen and Michael Meurer provided for the first time a comprehensive empirical evaluation of whether the patent system has produced good results in a paper<sup>8</sup> titled "Patent Failure." According to the empirical evaluation conducted by them, patents have not been able to give sufficient incentive to inventors at least in some industrial fields. In industries other than the chemical/pharmaceutical industries, costs have continued to significantly exceed earnings. The adverse effect thereof is significant particularly in the software industry.

As causes thereof, Bessen, et al. point out

that boundaries between rights are unclear and that there are too many small patents, <sup>12</sup> and see a decline in the notice function of patents (Patent Notice) as a problem. <sup>13</sup> As one of the measures to cope with too many patents, Bessen, et al. cite working on the problem of the quality of patents. <sup>14</sup> Although the problem of the quality of patents constitutes a mere part of the problems of the patent system, it has been pointed out as an important part.

In a paper<sup>15</sup> entitled "Patent Crisis," Burk and Lemley point out that the patent system is doing well in the pharmaceutical/biotechnology industries but that problems are arising in the IT industry. 16 The basic position of said paper emphasizes the necessity of changing the handling with respect to each industry under the situation where circumstances significantly differ in each industry and requiring the court to make appropriate determinations on a case-by-case basis.<sup>17</sup> Burk, et al. state that it is important for the court to make good use of policy levers<sup>18</sup> in the patent law and that the non-obviousness requirement is one of such policy levers. The characteristics of their analysis are emphasis on the roles of the court, and, for the problem of quality, expectations for the court setting appropriate standards are emphasized.

Differently from the fact that the government reports focused attention on the quality of patents, the quality of patents is understood as a mere part of the problems in scholars' papers. In addition, with regard to the substantive methods of strengthening monitoring of quality, scholars' papers explain roles which the court should play in detail. It seems to be very important to consider the problem of quality from both substantive and procedural perspectives while understanding it as no more than one problem in the large context.

## II Requirements for Patentability and Quality of Patents in the United States

#### 1 Regarding Requirements for Patentability in the United States and Their Significance

First of all, there is the patentable subject matter requirement. The requirement is attracting attention as Supreme Court judgments were rendered <sup>19</sup> <sup>20</sup> in recent years. This requirement is regarded as playing the role of providing for the scope of defense of the patent

law.

There are three requirements for obtaining a patent right in the United States, utility, novelty, and non-obviousness. These three requirements are considered as playing the role of directly controlling the "quality" of patent rights.

The utility requirement<sup>21</sup> can be understood as one that provides for the timing of grant of a patent right, that is, an invention becomes patentable only after its maturity reaches a certain level<sup>2223</sup>. This requirement, as same as the patentable subject matter requreiment, is rather playing the role of categorically excluding inventions with respect to each field of inventions.

The non-obviousness requirement is said to be the most important requirement among the substantive requirements for legal professionals who engage in patents. 24 If differences between a claimed invention and prior art are obvious to a person of ordinary skill in the art as of the filing, it is impossible to obtain a right for the invention. <sup>25</sup> patent non-obviousness requirement mainly assumes the role of deciding whether an invention is eligible for a patent. The novelty requirement is considered as functioning to give incentive for inventors to pursue not existing inventions but new inventions, 26 and it occupies an important place in the problem of the quality of patents. However, it is discussed in common with the non-obviousness requirement in many parts.

In order to obtain a patent right, it is also necessary that the claims and description fulfill the disclosure requirements (which refer to the enablement requirement and the written description requirement).<sup>27</sup> These requirements play the important role of limiting the scope to which the claims of a patent can be extended.<sup>28</sup> This is a problem relating to the form rather than the content of an invention.

According to the above, all of eligibility for a utility/novelty/non-obviousness patent, requirements, the enablement requirement, and written description requirement important requirements and are regarded as relating to the quality of patents. However, eligibility for a patent and the utility requirement categorically relate to the industrial and technical fields to which an invention pertains, and are slightly away from the quality of individual patents, on which this report focuses attention. In addition, although the disclosure requirements are important, they can be said to be relating to the method of writing a description rather than

the content of an invention. Consequently, it is considered beneficial to consider the problem, while focusing attention on novelty and non-obviousness, in particular, the non-obviousness requirement, in this report.

#### 2 Non-Obviousness Requirement in the United States and Its Significance

#### (1) Non-Obviousness Requirement

The novelty requirement requires that a claimed invention is not identical with prior art. However, the non-obviousness requirement denies patentability even if there are differences between a claimed invention and prior art if the differences are obvious to a person of ordinary skill in the art.

The fulfillment of the non-obviousness requirement is determined through the following process.<sup>29</sup> First of all, as matters of fact, (A) the scope and content of the prior art are decided, (B) differences between the claimed invention and the prior art are confirmed, and (C) the level of ordinary skill in the art is decided. (These are referred to as the "Graham factors".) Then, differences are whether the obvious determined based on these facts through a legal Objective decision. indicators relating inventions. which are called "secondary considerations," sometimes become of help in making such a determination.

In order to determine that an invention is obvious, the analysis that the invention is obvious should be made explicit. <sup>30</sup> Non-obviousness is determined on a case-by-case basis, and it is thus difficult to establish general determination standards. However, the typological patterns of analysis have been established. <sup>31</sup>

considerations are Secondary objective indicators that are used in determining non-obviousness. The examples thereof are commercial success, long-felt need, unexpected results. 32 They are considered as preventing "hindsight" and securing objective determinations.<sup>33</sup> However, there is a question of to what extent secondary considerations are connected the determination to of non-obviousness.34

## (2) Rationales for the Non-Obviousness Requirement

As a rationale for the non-obviousness requirement, it is said that patent-based incentive is not required to create an obvious idea.<sup>35</sup> This line of thought focuses on dividing inventions that

substantively require grant of an incentive and those that do not.

In addition, it is also explained that the non-obviousness requirement prevents incentive from diluting due to grant of patents to obvious inventions<sup>36</sup> and that the requirement is to cut costs for search and licensing by restraining the number of patents.<sup>37</sup> These explanations focus attention on the problem of transaction costs in the process of using inventions and instruct the necessity of reducing the number of patents.

Many scholars pay more attention to the first line of thought as a rationale that derives specific determination standards for non-obviousness. This idea can be classified into two types, a line of thought focusing attention on the content of inventions and a line of thought focusing attention on the processes through which an invention is created.

In the first type, the non-obviousness requirement is seen as a standard for sorting out inventions that require grant of an incentive.<sup>38</sup> This is a line of thought made through development of the "inducement standard" <sup>39</sup> indicated in the Graham decision. Duffy, etc. have developed the argument that this standard can be operated as a specific standard for determining obviousness.<sup>40</sup>

On the other hand, there is also a strong opinion that it is difficult to apply the inducement standard as a specific code of determination. Therefore, the idea of considering obviousness as a method of controlling inventors' inventive behaviors has developed. Merges asserts that the non-obviousness requirement changes inventors' behaviors and has the inventors venture into the creation of inventions of which patentability is unclear.41 Moreover, Meurer also points out the possibility that companies, etc. will tend to adopt research projects with low technical difficulty if protection by patents is not available, and states that optimum social conditions can be realized through protection of only those with high technical difficulty.42

According to the above, the results of analysis in theories are that patents should not be granted to all new inventions in order to give an appropriate incentive to inventors and that the number of inventions should be further reduced as a whole in consideration of the problem of subsequent transaction costs.

#### 3 Development of Case Laws Concerning the Non-Obviousness Requirement in the United States 43

#### (1) Outline

The non-obviousness requirement was put in the statutory form at the time of the enactment of the Patent Act of 1952. Then, a framework for determination of non-obviousness was established by the Graham decision. After that, the theory of non-obviousness has developed through the development of judgments in trials at lower courts. However, the theory of non-obviousness entered a new stage due to the KSR decision rendered by the Supreme Court in 2007.

## (2) Up to the Enactment of the Patent Act of 1952

Although novelty and utility have been consistently required since the Patent Act was enacted in 1790, non-obviousness has not been. Under the 1793 Act, it is interpreted that addition of "change in principle "44 is required to obtain a patent. This has developed into the non-obviousness requirement.

The Supreme Court judgment on *Hotchkiss v. Greenwood* <sup>45</sup> established a standard, that is, the "degree of skill and ingenuity" has to be more than the product of an ordinary engineer. <sup>46</sup> This judgment is meaningful in that it set up the direction of determining non-obviousness based on a person of ordinary skill in the art. However, at the same time, it is problematic that using "skill and ingenuity" as a standard was strictly interpreted in subsequent court precedents. The Cuno decision in 1942 came to determine that a "flash of creative genius" is required to obtain a patent. <sup>47</sup>

Act The 1952 provided for the non-obviousness requirement in Section 103 and clearly stipulated that a patent shall not be granted to an "obvious" invention. In addition, the second sentence of Section 103 clarified that the ability of the inventor and the manner in which the invention was made are irrelevant to patentability. This seemed to have lowered the standards for patentability that had become excessively high. However, how the new standards would be applied by the court remained unclear in some parts.

#### (3) Graham Decision and TSM Test

In 1966, the Supreme Court completed a framework for determination of non-obviousness

in the Graham decision.<sup>48</sup> In the Graham decision, the Supreme Court considered the Hotchkiss decision in 1851 as one that formulated general conditions for patentability, and understood that the Patent Act of 1952 also does not change the conventional general standards. On the other hand, the Supreme Court confirmed that the second sentence of Section 103 is generally understood as having the intention to abolish the "flash of creative genius" standard that was indicated in the Cuno decision.

The Graham decision made clear that determination of non-obviousness is made based on three facts, that is, the content and scope of the prior art, differences between the prior art and the claimed invention, and the level of a person of ordinary skill in the art. In addition, it also indicated that commercial success, etc. may serve as secondary considerations in determining non-obviousness.

Although the determination standards were made clear by the Graham decision, unclear points remained in terms of the specific scenes of application. After the CAFC was established in 1982 as a court which handles patent-related cases in a concentrated manner, the standards for determining non-obviousness started developing. Then, the "TSM standard" had been gradually formed at the CAFC as the only one standard for determining non-obviousness. TSM "teaching, suggestion or motivation." The content of the TSM standard is that teachings of references can be combined to obviousness only if there is some suggestion or incentive to do so.49

The TSM standard was accepted as the CAFC's standard for determining non-obviousness and has become established. This situation had been criticized in the FTC and NSF Reports as being excessively rigid, as mentioned above.

#### (4) KSR Decision<sup>50</sup>

The KSR decision is evaluated as a judgment that denied the conventional application of the TSM standard by the CAFC and drastically changed the direction of determination of non-obviousness.

The Supreme Court ruled that a court can consider the inferences and creative steps a person of ordinary skill in the art would employ, and clearly stated that it denies CAFC's rigid approach. Then, the Supreme Court stated that it can be important to identify a reason that would have prompted a person of ordinary skill in the

art to combine the elements but that helpful insights need not become rigid and mandatory formulas and if it is so applied, the TSM standard is incompatible with the Supreme Court's precedents.

The Supreme Court judgment denied determination of non-obviousness based on the conventional rigid framework, and confirmed that non-obviousness should be determined by reaching back to the principle of comprehensively determining whether an invention is obvious to a person of ordinary skill in the art.

#### (5) After the KSR Decision

It is said that the trends of judgments concerning determination of obviousness in the United States changed in response to the KSR decision. It is said that more applications and patents have been concluded as obvious as it has become possible to draw such conclusion more easily. <sup>51</sup> According to empirical study, the standards for non-obviousness clearly became stricter after the KSR decision, and patentability has become more easily deniable. The tendency of easier affirmation of obviousness is expected to continue in the future based on flexible standards.

# III System for Determination of Fulfillment of the Requirements for Patentability in the United States

#### 1 Outline of Legal Procedures Concerning Patents in the United States

The U.S. patent system also adopts the substantive examination principle. However, determination of fulfillment of the requirements for patentability in examination is nothing more than a rough "first screening," and there remains much room for disputing over the requirements for patentability even after the grant of a patent right.

As means of disputing over validity after the grant of a patent right, there are ex-parte reexamination, post grant review, and inter partes review (these are at the USPTO) as well as a defense of invalidity in an infringement action and a declaratory judgment action of invalidity (these are at the court).

The United States Patent and Trademark Office (USPTO) and the federal courts (Federal District Courts, Court of Appeals for the *Federal Circuit* (CAFC), and Supreme Court) mainly engage in patent-related procedures in the United States. At the USPTO, there are procedures

conducted by examiners and those conducted by the Patent Trial and Appeal Board (PTAB). The PTAB is an administrative body but is a body similar to the court, and administrative judges make determinations.<sup>53</sup> Actions can be filed with the Federal District Courts around the country. Appeals from the PTAB or District Courts are concentrated in the CAFC. The Supreme Court is above the CAFC, and it is pointed out that its influence has been increasing in recent years.<sup>54</sup>

#### 2 Examination

The request for examination system does not exist in the United States,<sup>55</sup> and examination is necessarily conducted if an application is filed in a given format. All the requirements for patentability are subject to examination, but the hours of examination per application are very limited. A system of information provision by third parties was established by the AIA.

The examination of the non-obviousness requirement starts with an examiner's showing "prima facie obviousness." An examiner bears the burden of proof that requires first showing prima facie obviousness, and a patent is granted if the examiner cannot show it. A clear demonstration is required for an examiner to show obviousness. The final proof of obviousness by an examiner requires a "preponderance of evidence," and the examiner has to show it while including evidence submitted by the applicant.

Examiners are technical specialists. An applicant can file an appeal with the PTAB if he/she is dissatisfied with an examiner's determination. At the PTAB, the applicant can obtain a determination by an administrative judge who has expertise in both patent law and technology.

#### 3 Ex-Parte Reexamination

Ex-parte reexamination is a system by which one can request the USPTO for the reexamination of a patent by citing prior arts that are related to the patentability of the patent.<sup>59</sup> Any person, including a patentee, can file a request for reexamination.

A "substantial and new question of patentability" <sup>60</sup> must be shown for the commencement of an ex-parte reexamination. The requirements for patentability that can be reviewed in an ex-parte reexamination are the novelty and non-obviousness requirements.

Ex-parte reexamination can be said to be the most simple and convenient procedure for disputing over patentability again after the grant of a patent. The requirements for commencing the procedure are not high. In addition, a third party can perform the procedure under anonymity, and the parties are never bound by estoppel in an action. However, the degree to which a third party can engage in the procedure is very limited.<sup>61</sup>

#### 4 Post Grant Review

The post grant review (PGR) system was established through the 2011 Revision. Any person other than the patentee may file a petition for a PGR within nine months from the date of the grant of the patent.<sup>62</sup> Almost all requirements for patentability can be subject to a PGR.<sup>63</sup>

The requirement for the commencement of a PGR is that information presented in a petition, if such information is not rebutted, demonstrates that it is "more likely than not" that at least one of the claims is unpatentable.<sup>64</sup>

The proceeding of a PGR is carried forward at the PTAB based on conflict between two parties.<sup>65</sup> In a PGR, it has become possible to use discovery in the same manner as in an action. However, the subject of discovery is limited.<sup>66</sup> In a PGR, a petitioner bears the burden of proving unpatentability. Presumption of validity does not work, and it is only necessary to prove it by a "preponderance of evidence."<sup>67</sup>

Estoppel is imposed on the parties who have received a final decision in a PGR.<sup>68</sup> The rise of estoppel can be one of the disadvantages for a petitioner of a PGR.

Through a PGR, it is possible to go through a relatively careful proceeding in that a petitioner can receive a determination made by an administrative judge under a structure similar to the court and that discovery is also possible, though the proceeding is simpler than that at the court. On the other hand, in terms of costs, costs for a PGR are considerably lower than those for an action.<sup>69</sup> Therefore, PGR can be evaluated as a procedure possessing the good features of procedures at the court and ex-parte reexamination.

#### 5 Inter Partes Review

Inter partes review (IPR) is a procedure that was newly established by the AIA. Any person can file a petition for IPR after nine months have passed since the date of the grant of a patent (after the nine months, a petition for a post grant review cannot be filed). Reasons that can be disputed are limited to the novelty or non-obviousness requirement based on prior art consisting of patents or printed publications. As for the requirement for the commencement of an IPR, commencement of the procedure is decided when there is a "reasonable likelihood" that the petitioner would prevail with respect to at least one of the claims.

The proceeding of an IPR is also carried forward at the PTAB based on conflict between two parties. In addition, discovery is available. However, the subject of discovery is limited in the same manner as PGR, and the limitation is stricter than PGR. In an IPR, a petitioner also bears the burden of proving unpatentability, and it is only necessary to prove it by a "preponderance of evidence."

In an IPR, estoppel is also imposed on the parties who have received a final decision, in the same manner as in a PGR.

IPR has characteristics in common with PGR. It can be summarized as a procedure by which it is possible to go through a relatively fulfilling proceeding more simply and at a lower cost<sup>76</sup> than at the court.

#### 6 Defense in an Infringement Action and Declaratory Judgment Action of Invalidity

In a patent infringement action, the alleged infringer can make a defense to the effect that the action should be dismissed as the patent is invalid. In addition, the alleged infringer can also receive a declaratory judgment to the effect that the patent is invalid. That is, a declaratory judgment as remedy for a party is acknowledged in the United States,<sup>77</sup> and this remedy is also available for the validity of a patent.

It has been understood in the past that a "reasonable threat" that one will face an infringement action is necessary to institute a declaratory judgment action of invalidity. <sup>78</sup> Therefore, cases where an action can be instituted were limited. However, the MedImmune decision in 2007 changed the CAFC's conventional precedents, <sup>79</sup> and thereby, the possibility of being able to institute a declaratory judgment action was expanded.

As it may be presumed that a patent is valid,<sup>80</sup> the party against the patentee is to bear the burden of proving facts that serve as the basis

for invalidity. In order to reverse such presumption, it is necessary to prove invalidity with "clear and convincing evidence." 8182

As these procedures are carried out at the court, discovery can be used in the same manner as ordinary civil actions, and a determination by a judge can be obtained. However, District Courts in charge of the first instance involve instability due to problems such as jury and forum shopping. Furthermore, costs for these procedures are dramatically higher than those for procedures at the USPTO.<sup>83</sup>

#### 7 Summary

Through procedures at the USPTO, it is possible to dispute over the invalidity of a patent simply and at a low cost, and a specialized, stable determination can be easily obtained. On the other hand, there are certain limitations on usable evidence and reasons that can be disputed. Procedures at the court have disadvantages, specifically, heavy costs and labor. In addition, hurdles are high for the timing when the procedures are available as well as for proof of invalidity. However, there are advantages, specifically, one-time settlement together with an infringement action and availability of discovery.

#### IV Suggestions for Japanese Law

#### 1 Inventive Step Requirement in Japan

#### (1) Inventive Step Requirement

Under Japanese law, determination inventive step is made based on a framework consisting of (1) finding of the invention in question, (2) finding of the cited invention, (3) finding of points of identity and difference between the invention in question and the cited invention, and (4) determination concerning the points of difference (determination of whether the invention in question could have been easily arrived at).84 Processes (1) to (3) are findings of facts that serve as premises of a determination, 85 and determination in (4) is made based on those facts. Determination in (4) is made based on a person of ordinary skill in the art. Therefore, the content of knowledge of a person of ordinary skill the art ("common general technical knowledge") 86 is also a fact that serves as a premise of determination in (4).87 Consequently, facts that serve as premises of determination of whether the invention in question could have been easily arrived at in (4) are the invention in question, the cited invention, and common general technical knowledge, which correspond to the three factual factors pointed out in the Graham decision in the United States.

In order to show that the invention in question could have been easily arrived at in Japan, it is necessary to demonstrate (establish a logical argument) that the invention in question could have been easily made. 88 If one can establish such a demonstration in a rational manner, inventive step is denied. On the other hand. if cannot establish such one demonstration in a rational manner, inventive step is affirmed.89 Though inventive step is denied if demonstration of the fact that the invention in question could have been easily arrived at succeeds, there are some established patterns of demonstration. The patterns of establishing a logical argument are similar to those in U.S. practice. Moreover, although an indicator, "advantageous effect (unexpected effect)," is often used,90 this functions in the same manner as secondary considerations in the United States.

In the current practice of determination of inventive step at the Intellectual Property High Court, it is required to demonstrate a motivation, that is, the fact that a person of ordinary skill in the art could have easily arrived at the invention in question, by specifically indicating the existence of a suggestion, etc. This was brought about by a recent change in the trends of judgments. The inventive step requirement in Japan has become increasingly relaxed while the non-obviousness requirement in the United States has become stricter. Thereby, both countries are meeting halfway.

#### (2) System for Determination

There are also some systems to dispute over inventive step in Japan. However, options in Japan are considerably simpler than in the United States. There are examination, trial for invalidation, and defense of invalidity in an infringement action.

It can be said that the quality of examination in Japan is higher than the United States; however, even so, examination is not conducted over a long time. In Japan, there is an established mechanism to check fulfillment of the requirements for patentability again after the grant of a patent, in the same manner as the United States.

Any person can file a request for a trial for invalidation after the grant of a patent.<sup>92</sup> In a trial for invalidation, parties can receive the

proceedings through procedures equivalent to a civil action. The fee for filing a request for a trial for invalidation is considerably lower than that in the United States. Differently from ex-parte reexamination in the United States, the trial for invalidation system is cumbersome, as one who has filed a request for a trial for invalidation has to engage in the trial as a party. A system that makes examination by documentary proceeding a principle is not available at present. Costs for a trial for invalidation are considerably lower than those for a PGR and IPR, and the trial for invalidation system is one that enables parties to easily receive fulfilling proceedings.

Though it is permitted to make a defense of invalidity in an infringement action, <sup>95</sup> it is impossible to institute a declaratory judgment action of invalidity with the court in Japan. <sup>96</sup> Determination of invalidity in Japan is nothing more than determination made in the reasons for the judgment, and thus does not have res judicata. In addition, neither estoppel nor any other effect arises in principle.

## 2 Suggestions for Japanese Law Made by U.S. Law

Substantive standards in Japan and those in the United States have been getting closer. It is necessary to continuously be conscious of the balance between appropriate elimination of hindsight and securing of the quality of patents in making a determination.

A variety of options for systems for the examination of patentability are available in the United States. On the other hand, trial for invalidation is almost the only option in Japan. However, it is a considerably user-friendly and all-round system.

#### 3 Future Prospects

With regard to the inventive step and non-obviousness standards, it is important to establish standards that adequately restrain the number of patents while avoiding the problem of entrance of hindsight. It is necessary to accurately understand problems by more empirically studying the trends of determination of inventive step in Japan. It is necessary to consider the trends of determination of inventive step and changes in the ratio of patents being invalidated in more detail. Moreover, it is necessary to verify whether differences in the

trends of determination between Japan and the United States have actually ceased to exist through these works.

With regard to procedural aspects, it is necessary to develop discussions on an institutional design that is desirable for maintaining high-quality patent rights, based on empirical data in Japan and the United States.

- <sup>1</sup> For example, the quality of a patent may be defined as indicating to what extent a patent substantively contributes to the development and disclosure of a new technology or the economic value of a patent (Ronald J. Mann and Marian Underweiser, *A New Look at Patent Quality: Relating Patent Prosecution to Validity*, Journal of Empirical Legal Studies vol.9 Issue 1 1(2012)). In this report, the definition as mentioned in the text was adopted in the same manner as in Mann & Underweiser (2012).
- <sup>2</sup> Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (October 2003)
- National Academy of Science, A Patent System for the 21st Century (2004)
- <sup>4</sup> eBay Inc. v. MercExchange, LLC, 547 U.S. 388 (2006)
- <sup>5</sup> Lucent technology v. Gateway Inc., 580 F.3d 1301 (Fed. Cir. 2009)
- <sup>6</sup> KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007)
- <sup>7</sup> Through the revision of Section 102 of the patent law, the standard time for determination of novelty was changed from the time of making an invention to the effective filing date. However, it is necessary to note that the change comes with the later-mentioned one-year grace period.
- <sup>8</sup> James Bessen & Michael J. Meurer, PATENT FAILURE: HOW JUDGES, BUREAUCRATS AND LAWYERS PUT INNOVATORS AT RISK (Princeton University Press, 2008) (hereinafter cited as "Bessen & Meurer (2008)").
- <sup>9</sup> Bessen & Meurer (2008) at 3.
- <sup>10</sup> Bessen & Meurer (2008) at 106-109, 138-142.
- 11 Bessen & Meurer (2008) at 187-194.
- 12 Bessen & Meurer (2008) at 10.
- 13 Bessen & Meurer (2008) at 18.
- 14 Bessen & Meurer (2008) at 26, 247.
- Dan L. Burk and Mark A. Lemley, PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (The University of Chicago Press, 2009) (hereinafter cited as "Burk & Lemley (2009)").
- <sup>16</sup> Burk & Lemley (2009) at 3-5.
- Burk & Lemley (2009) at 5, 95-108. As the bases thereof, said paper points out that industry-specific lawmaking brings about the problem of compliance with the TRIPS Agreement and that the enactment of the Patent Reform Act was running into difficulties at Congress, as well as the institutional superiority of the court.
- Burk & Lemley (2009) at 109-130. Burk and Lemley had already shown the idea of policy levers in an earlier paper, and thereby indicated that it is possible to control patent policy by the court's raising and lowering the determination standards for various requirements that exist in the patent law (Dan L. Burk

- and Mark A. Lemley, Policy Levers in Patent Law, 89 VA. L. REV. 1575, 1688 (2003)).
- Bilski v. Kappos, 130 S. Ct. 3218, 561 US \_\_, 177 L. Ed. 2d 792 (2010). Claim 1 claimed a method for hedging risk. In the judgment, the court denied eligibility for a patent, deeming the method to fall under an abstract idea. The judgment is worthy of attention in that it did not deny the "machine or transformation test" which the CAFC had adopted as a method of determining whether an invention falls under a "process" but determined that the test is not the only one determination method and that it did not adopt the opinion of Justice Stevens, etc. that categorically excludes business methods from patentability.
- Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. \_\_\_ (2012). The invention in question was related to a drug for autoimmune diseases, thiopurine. It is a method of measuring the amount of metabolites in the blood of a patient to whom thiopurine has been administered and adjusting the dose depending on the measured amount. In the judgment, the court determined that the claim is nothing more than a natural law that indicates the correlations between metabolites and dose, and denied protection by patent.
- According to Robert P. Merges and John F. Duffy, PATENT LAW AND POLICY: CASE AND MATERIAL 5TH EDITION (LexisNexis, 2012) at 211, a phrase in Section 112 ("as to enable ... <u>use</u> the same") is also considered as requiring the existence of utility in an invention.
- <sup>22</sup> Brenner v. Manson, 383 U.S. 519 (1966).
- <sup>23</sup> See Merges and Duffy supra note 21 at 256-259. It indicates through economic analysis that it is beneficial to grant a patent at a relatively early stage (therefore, based on loose standards for utility).
- For example, it is indicated as the "ultimate condition of patentability" in John F. Witherspoon ed., NONOBVIOUSNESS- THE ULTIMATE CONDITION OF PATENTABILITY (1980).
- <sup>25</sup> Section 103 of the patent law: A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made
- Robert P. Merges and John F. Duffy, PATENT LAW AND POLICY: CASE AND MATERIAL 5TH EDITION (LexisNexis, 2012) at 428.
- <sup>27</sup> 35 U.S.C. 112 Specification
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- <sup>28</sup> Merges and Duffy supra note 21 at 265.
- <sup>29</sup> Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459

- (1966).
- <sup>30</sup> In re Kahn, 441 F.3d 977, 988 (CA Fed. 2006), KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 418 (2007).
- 31 The following add-up is based mainly on the add-up of MPEP §2142.
- <sup>32</sup> Graham v. John Deere Co., 383 U.S. 1, 18(1966).
- <sup>33</sup> Gore v. Garlock 721 F.2d 1540 , 1553(Fed. Cir. 1983) points out that secondary considerations act as "insurance" against errors due to hindsight.
- <sup>34</sup> Robert P. Merges, Economic Perspective on Innovation: Patent Standards and Commercial Success, 76 Cal. L. Rev. 803 (1988).
- $^{35}$  Merges and Duffy supra note 21 at 622-624.
- <sup>36</sup> Id. at 623.
- <sup>37</sup> Id. at 624.
- The line of thought introduced here was indicated mainly in Michael Abromowicz and John F. Duffy, The Inducement Standard of Patentability, 120 Yale L.J. 1590 (2011).
- <sup>39</sup> Graham v. John Deere Co. 383 U.S. 1, 11 (1966).
- <sup>40</sup> Abromowicz and Duffy supra note 38 at 1596.
- <sup>41</sup> Robert P. Merges, Uncertainty and the Standard of Patentability, 7 High tech. L. J. 1 (1993).
- <sup>42</sup> Michael J Meurer and Katherine J. Strandburg, Patent Carrots and Sticks, 12 Lewis & Clark L. Rev. 547 (2008).
- Edmund Kitch, Graham v. John Deere Co.: New Standards for Patents, 1966 SUP. CT. REV. 293(1966) is informative with regard to the development before the Graham decision, though it is old. This report is mainly based on John Duffy and Robert P. Merges, The Story of Graham v. John Deere Company: Patent Law's Evolving Standard of Creativity in INTELLECTUAL PROPERTY STORIES (Jane C. Ginsburg and Rochelle Cooper Drevfuss ed., 2006).
- 44 Evans v. Eaton, 20 U.S. 356 (1822).
- 45 Hotchkiss v. Greenwood, 52U.S.(11 How.)248 (1851).
- <sup>46</sup> Id. at 267.
- <sup>47</sup> Cuno Engineering Corp. v. Automatic Devices Corp., 314 U.S. 84 (1941).
- 48 Graham v. John Deere Co., 383 U.S. 1, 18(1966).
- <sup>49</sup> ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572 (Fed. Cir. 1984), Al-Site Corp. v. VSI International, Inc. 174 F.3d 1308 (Fed. Cir. 1999).
- <sup>50</sup> KSR International CO. v. Teleflex Inc. 550 U.S. 398 (2007).
- Jennifer Nock & Sreekar Gadde, Raising the Bar for Nonobviousness: An Empirical Study of Federal Circuit Case Law Following KSR, 20 Fed. Cir. B.J. 369 (2011).
- Merges and Duffy supra note 21 at 1046. However, presumption of validity is obtained pursuant to 35 U.S.C. § 282.
- Administrative judges are not equivalent to ordinary judges (called "Article III Judge" in the United States with its origin in Article III of the Constitution) but Article I Judge, and the consent of the Senate is not required for their appointment.
- John F. Duffy, The Festo Decision and the Return of the Supreme Court to the Bar of Patents, 2002 S.Ct. Re. 273 (2003) (which points out the role which the Supreme Court played in forming case law for patents).
- 55 However, 37 C.F.R. 1.103(d) sets the examination

- deferral system, and on request of the applicant, a deferral of examination may be granted for a period not exceeding three years.
- <sup>56</sup> In re Linter 458 F.2d 1048 (CCPA 1976), MPEP§2142.
- <sup>57</sup> See supra note 30.
- <sup>58</sup> MPEP§2142.
- <sup>59</sup> 35 U.S.C. § 301 and 302.
- <sup>60</sup> If a reference is presented in a new light, it may be regarded as raising a substantial and new question, even if it has already been reviewed at the USPTO (MPEP§2216).
- 61 After the commencement of reexamination is decided, the patentee may file a statement, and a person who has requested reexamination may file a reply thereto. After such exchange ends, examination by an examiner starts (35 U.S.C. §304). A person who has requested reexamination can engage in the procedure to a certain extent by filing such a reply, but his/her engagement is still limited.
- 62 35 U.S.C. § 321.
- 63 35 U.S.C. § 322(b). § 282(b)(2)(3) provides for reasons which can be submitted as a defense of invalidity in an infringement action, and the reasons listed there can be used as reasons for opposition. It is possible to dispute over utility, novelty, inventive step, non-obviousness, and the written description requirement under § 112 (excluding the best mode requirement) as well as the requirements for application for reissue in the case of application for reissue.
- <sup>64</sup> 35 U.S.C. § 324(a). However, upon a petition, the patentee may file a preliminary response to the petition (§ 323). This positioning is mentioned later.
- 65 35 U.S.C. § 326(c).
- 66 35 U.S.C. § 326(a)(5) and 37 CFR 42.51-.
- 67 35 U.S.C. § 326(e).
- 68 35 U.S.C. § 325(e)(1)(2).
- <sup>69</sup> Where the number of claims is 20 or less. \$600 is added with respect to each claim. An action in which the value of the subject-matter is less than \$1 million costs \$0.35 million up to discovery and \$0.65 million for the entire action. An action in which the value of the subject-matter is \$25 million or more costs \$3 million up to discovery and \$5 million for the entire action (2011 Report of the Economic Survey, American Intellectual Law Association).
- <sup>70</sup> 35 U.S.C. § 311.
- <sup>71</sup> 35 U.S.C. § 311(b).
- <sup>72</sup> 35 U.S.C. § 314(a).
- <sup>73</sup> 35 U.S.C. § 316(c).
- <sup>74</sup> 35 U.S.C. § 316(a)(5).
- <sup>75</sup> 35 U.S.C. § 316(e).
- <sup>76</sup> See supra note 69.
- <sup>77</sup> Declaratory Judgments Act 28 U.S.C.
- <sup>78</sup> C.R. Bard, Inc. v. Schwartz, 716 F.2d 874 (Fed. Cir 1983), Teva Pharms. USA, Inc v, Pfizer Inc., 395 F.3d 1324 (2005).
- <sup>79</sup> MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007).
- 80 35 U.S.C. § 282(a).
- Also see Microsoft Corp. v. i4i Limited Partnership, 131 U.S. 2238 (2011) and Donald S. Chisum, 2-5 CHISUM ON PATENTS §19.02 (2012).
- 82 35 U.S.C. § 282(a).

83 See supra note 69.

- Examination Guidelines for Patent and Utility Model in Japan, Part II, Chapter 2 Novelty and Inventive Step. In the judgment of the Tokyo High Court of October 15, 2002 (1999(Gyo-Ke)102), the court states that this framework is a reasonable and established method.
- 85 However, it is necessary to note that finding of the invention in question is not finding of a fact in a pure sense as it includes a legal decision, that is, claim interpretation.
- According to the Examination Guidelines, Part II, Chapter 2, 1.2.4(3), "common general technical knowledge" means "obvious knowledge derived from the general knowledge or experience of a person skilled in the art."
- Note that to what extent the content of knowledge is included in common general technical knowledge is a legal decision though the content of knowledge itself is a fact.
- Examination Guidelines, Part II, Chapter 2, 2.4. Also see judgment of the Intellectual Property High Court, December 28, 2007, 2007(Gyo-Ke)10027.
- Nobuhiro Nakayama and Naoki Koizumi, ed., Shin Chukai Tokkyoho (New Patent Act with notes) (Seirin Shoin, 2011), 261-263 [Naito and Sakai (Jiro)] and Takeshi Maeda and Junko Kobayashi, "Shinposei handan no hoteki na kozo" (Legal structure of determination of inventive step), Patent, vol. 63, no. 7 (2010); 119 and 125-126.
- Maeda and Kobayashi supra note 89. Incidentally, in the Inventive Step Study Committee Report, an advantageous effect is subtly differently positioned between the cases of combination and replacement and the cases of design variation, etc. This is probably because of the idea that a mere design variation, etc. may be determined to have been easily arrived at even with an advantageous effect. However, what effect can be said to be "advantageous" and "unexpected" is not a matter of fact but a matter of evaluation. Therefore, consistency can probably be secured even without drawing a distinction as in the report if it is summarized that a hurdle for recognizing a mere design variation, etc. as "advantageous" is higher.
- <sup>91</sup> Judgment of the Intellectual Property High Court, January 28, 2009, *Hanji*, no. 2043, at 117 [Connecting member for circuit].
- 92 Article 123, paragraphs (1) and (2) of the Patent Act. However, only a true right holder can file such a request for the reason of misappropriation. Any person can file such a request for the reason of violation of the inventive step requirement.
- 93 See Articles 131 to 156 of the Patent Act.
- <sup>94</sup> See the Minutes of the 35th Meeting of the Patent System Subcommittee of the Industrial Structure Council. The "post grant review" system of which introduction is suggested therein is a user-friendly system like the former post-grant opposition system centering on examination by documentary proceeding.
- 95 Article 104-3, paragraph (1) of the Patent Act.
- <sup>96</sup> See the judgment of the Supreme Court, April 23, 1917, *Minroku*, vol. 23, at 654.