Research and Study concerning Differences in Determination of Unity of Invention among IP5 offices

The First International Affairs Committee
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Abstract: In recent years, the patent offices of major countries have been actively working on harmonizing their patent systems. Since unity of invention is one of the key issues addressed through such transnational efforts, the First International Affairs Committee, one of the expert committees organized under the Japan Intellectual Property Association (JIPA), surveyed the situation of patent prosecution in some major countries. Our survey ascertained that the percentage of recognizing lack of unity of invention in the first action was exceptionally high in the United States. We would like to explain this peculiarity in US patent prosecution, and hope that this document will assist in the practical patent management of JIPA members. This document also introduces our suggestions for achieving patent system harmonization.

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1. Introduction

With the progress of globalization of business, enterprises are becoming increasingly willing to file patent applications internationally for each invention. The international convergence of patent systems (including patent filing procedures and the criteria for judging patentability) is keenly awaited by industry; if it is achieved, enterprises will be able to

reduce filing costs and more accurately predict the possibility of successful patent registration. To keep up with this trend, the Five IP Offices (IP5), i.e., the patent offices in Japan, the US, the EU, China, and Korea, have recently been working on harmonizing their patent systems. As part of such efforts, the IP5 agreed in the Meeting of IP5 Heads of Office held on June 6, 2014 that the IP5 would focus discussions on the three key issues for the harmonization of patent systems: written description and sufficiency of disclosure, citation of prior art, and unity of invention.[1)] In the wake of this IP5 agreement, we conducted a fact-finding survey on unity of invention, the theory of which had not yet been supported by actual circumstances, in order to identify differences among the IP5 patent offices in terms of the assessment of unity of invention. Then, we examined some differing tendencies identified in the survey.

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2. Comparison of Statutory Provisions Concerning Unity of Invention

Table 1 compares the provisions concerning unity of invention enforced in the respective countries (including a region and a treaty): Japan, the US, the EU, China, Korea, and the Patent Cooperation Treaty (PCT).

With regard to patent applications in the US (excluding those entering the phase of international application under the PCT), there is no concept of unity of invention. However, the provisions concerning restriction and election of species in the US patent laws are treated as the provisions concerning unity of invention for the purpose of comparison of the provisions adopted by the respective countries. Therefore, in all subsequent descriptions in this document explaining patent prosecution in the US, the term “unity of invention” includes the concept of restriction/election of species when it is used in such expressions as “failure to fulfill the unity of invention requirement,” “non-compliance with the requirement of unity of invention,” “finding of lack of unity of invention,” or the like.

Table 1: Comparison of Statutory Provisions Concerning Unity of Invention

	Underlying provision of the relevant law	Essence of the referenced provision
JP	Article 37 of the Patent Act Article 25-8 of the Ordinance for Enforcement of the Patent Act	If two or more inventions have common "special technical features," a group of those inventions is determined to fulfill the requirement of unity of invention.
US	35 U.S.C. 121 (US patent law) 37 CFR 1.141 (US patent regulations)	"Independent and distinct inventions" are determined to lack unity of invention.
EU	Article 82 of the European Patent Convention (EPC) Rule 44(1) of the Implementing Regulations of the Convention	If a patent application relates to one invention only or to "a group of inventions so linked as to form a single general inventive concept," the requirement of unity of invention is determined to be fulfilled.
CH	Article 31 of the Patent Law Rule 35 of the Implementing Regulations of the Patent Law	Two or more inventions embodied in a single general invention concept may be determined to fulfill the unity of invention requirement.
KR	Article 45(1) of the Patent Act Article 6(1) of the Enforcement Decree of the Patent Act	A group of inventions so linked as to form a single general inventive concept may be claimed under one patent application.
PCT	Article 17(3)(a) of the PCT Rule 13 of the Regulations under the Patent Cooperation Treaty	The requirement of unity of invention will be fulfilled only when there is a technical relationship among two or more inventions involving one or more of the same or corresponding special technical features.

Looking into the provisions concerning unity of invention enforced in the respective countries, Japan, the EU, China, Korea, and the PCT adopt a common approach to judge unity of invention, regardless of slight differences in details. Their judgments are based on whether or not there is a special technical feature (STF) making a contribution over the prior art.

On the other hand, the US patent law says that independent and distinct inventions lack unity of invention, without considering whether there is an STF or not (MPEP 806.02).

According to the first criterion that an examiner must satisfy to issue a notice of the reasons for rejection on the grounds of lack of unity of invention under MPEP 803, the claimed inventions must be independent or distinct inventions. In other words, the examiner need only show either independence or distinctness. While 35 U.S.C. 121 (US patent law) and 37 CFR 1.141 (US patent regulations) stipulate that independent and distinct inventions are determined to lack unity of invention, the USPTO has been adopting a practice of explaining either independence or distinctness, not both, in its examination procedure, in light of the development of legislation (MPEP 802.01). The second criterion to determine lack of unity of invention under MPEP 803 is whether there would be a serious burden in the examination procedure, which is a seemingly abstract criterion. However, the guidelines described in MPEP 808.02 expressly mention the three requirements to establish a serious burden: (A) separate classification, (B) separate status in the art, or (C) different field of search. Therefore, the examiner must demonstrate that the claimed inventions meet at least one of

these three requirements. In practice, separate classification (pattern A) seems to be the most frequently used reasoning to show a serious burden and issue a notice of the reasons for rejection on the grounds of lack of unity of invention.

Table 2 indicates the provisions concerning examination of unity of invention in the laws and regulations of the respective countries which are applicable to PCT applications entering the national or regional phase. Japan and Korea have no particular provisions in this respect. Under the provisions enforced in the EU and China, the adequacy of a finding of non-compliance with the unity of invention requirement in the international phase is supposed to be checked in order to determine whether or not to carry out the examination process for the claims for which an additional search fee was not paid in the international phase. These provisions correspond to Article 17(3)(b) of the PCT. In other words, applications directly filed with the national or regional patent office ("non-PCT applications") also are controlled by the provisions equivalent to the judgment criteria under the PCT in Japan, the EU, China, and Korea. In these countries, therefore, there is substantially no difference between PCT applications and non-PCT applications when they are treated by the national patent or regional patent office.

In contrast, 35 U.S.C. 372(b)(2) (US patent law) stipulates that the Director may cause the question of unity of invention to be reexamined under section 121, within the scope of the requirements of the treaty and the Regulations, after the PCT application enters the US national phase. This provision means that unity of invention may be reexamined in the US national phase, regardless of whether lack of unity of invention has been found or not in the international phase. However, such reexamination is supposed to be limited to the scope of the requirements of the treaty and the Regulations. This means that the USPTO's reexamination of unity of invention must be based on the PCT criteria.

Table 2: Provisions Concerning Examination of Unity of Invention for PCT Applications

	Underlying provision of the relevant law	Essence of the referenced provision
JP	N/A	N/A
US	35 U.S.C. 372(b)(2) (US patent law) 37 CFR 1.475, 1.499 (US patent regulations)	The Director may cause the question of unity of invention to be reexamined under section 121, within the scope of the requirements of the treaty and the Regulations.
EU	Rule 164 of the Implementing Regulations of the European Patent Convention	If the examiner considers that the application documents do not comply with the requirement of unity of invention, the examiner will inform the applicant that a further search fee must be paid within a period of two months, and then the examiner will draw up the supplementary European search report for the parts of the application relating to inventions in respect of which search fees have been paid.

	Underlying provision of the relevant law	Essence of the referenced provision
CH	Rule 115 of the Implementing Regulations of the Patent Law	If some parts of an international application enter the Chinese national phase without going through international search or international preliminary examination and the applicant requests that such parts be the basis of examination, the competent office must give notice to direct the applicant to pay the restoration fee for unity of invention within the specified time limit.
KR	N/A	N/A
PCT (for reference)	Article 17(3)(b) of the PCT	The national law of any designated state may stipulate that the relevant parts of the international application shall be considered withdrawn unless the applicant pays a special fee to the competent office of that state.

As a result of comparing the provisions concerning unity of invention enforced in the respective countries, as explained above, the US applies its own judgment criteria to non-PCT applications and the criteria compatible with those of Japan, the EU, China, and Korea to PCT applications. Under the latter criteria, whether there is an STF or not is checked to judge unity of invention. For reference, the provisions concerning unity of invention in the US patent law are excerpted in Table 3.

Table 3: Provisions Concerning Unity of Invention in the US Patent Law

Underlying provision of the relevant law	Essence of the referenced provision
35 U.S.C. 121 (US patent law)	Independent and distinct inventions are determined to lack unity of invention.
37 CFR 1.141 (US patent regulations)	Two or more independent and distinct inventions may not be claimed in one national application.
MPEP 803	If an examiner intends to require that an application be restricted to one of the claimed inventions, those plural inventions must be patentably distinct inventions meeting the following criteria: (A) Those inventions must be independent or distinct. (B) There would be a serious burden on the examiner if restriction is not required.
MPEP 808.02	In order to explain why there would be a serious burden on the examiner, the examiner must show one of the following: (A) Separate classification (B) Separate status in the art (C) Different field of search
35 U.S.C. 372(b)(2) (US patent law)	With regard to a PCT application, the Director may cause the question of unity of invention to be reexamined under section 121, within the scope of the requirements of the treaty and the Regulations.
37 CFR 1.475 (US patent regulations)	When a group of inventions claimed in one PCT application forms a “single general inventive concept” and involves one or more STFs, this application is determined to fulfill the unity of invention requirement.

3. Statistical Survey Concerning Unity of Invention Examinations

For the purpose of grasping actual examinations of unity of invention by the respective national patent offices, we gathered their patent prosecution data and attempted to understand an overall trend through a statistical approach.

3.1 Preconditions for the Survey

The application filings to be surveyed were chosen in accordance with the following conditions.

(1) Countries surveyed

Patent application examinations in

Japan, the US, the EU, and China were surveyed. Korea was excluded from the survey described in this Section 3 since it was difficult to gather Korean file wrapper information.

(2) Time periods surveyed

For the purpose of analyzing examination activities performed during the same time span, we tried to set a specific time period. We initially intended to preferably choose patent applications for which the first action had been issued during the period from October 1, 2013 to December 31, 2013. In reality, however, we could not use the same conditions for choosing data from all the surveyed countries because of restrictions arising from the functionality of their respective databases. Alternatively, we chose patent applications under the conditions described below, which were determined in light of the average first action period of each country. Due to the same restriction, US applications were chosen separately from non-PCT applications and PCT applications.

(i) Japan

Patent applications for which the first action was issued during the period from October 1, 2013 to December 31, 2013

(ii) US (non-PCT applications)

Patent applications filed during the period from April 1, 2012 to June 30, 2012 and pending on September 30, 2013

(iii) US (PCT applications)

Patent applications filed during the period from October 1, 2010 to December 31, 2010 and pending on September 30, 2013

(iv) EU

Patent applications for which an extended European search report and a partial search report had been issued during the period from October 1, 2013 to December 31, 2013

(v) China

Patent applications for which a request for examination had been filed during the period from October 15, 2012 to January 15, 2013 and which were pending on September 30, 2013

(3) Classification of inventions and numbers of surveyed applications

The patent applications meeting the conditions described above were chosen at random in accordance with the following classification:

I. Electrical engineering	500
II. Instruments	500
III. Chemistry	500
IV. Mechanical engineering	500

(applications in each country)

The identification of these areas complies with the technology classification specified in the IPC and Technology Concordance Table, which has been prepared based on the International Patent Classification (IPC) established by the World Intellectual Property Organization (WIPO).

(4) Survey content and judgment criteria

We reviewed the patent applications chosen in the way described above, in order to check whether or not a judgment about unity of invention had been exhibited in the first action. Then, we analyzed differences by country and by category (technology area) through comparing the percentages of applications facing such judgment.

3.2 Survey Results

Table 4 and Figure 1 indicate the percentages of patent applications resulting in a finding of lack of unity of invention by category and by country.
Our comparison by country discovered that the US had an extremely high percentage of applications resulting in a finding of lack of unity of invention in each of the specified categories. We also found that both PCT applications and non-PCT applications in the US showed almost the same percentage resulting in a finding of lack of unity of invention.

Looking into the percentages by category, the area of chemistry showed a high percentage in each country. Among others, in the US over 50% of applications resulted in a finding of lack of unity of invention, which is a noteworthy figure.

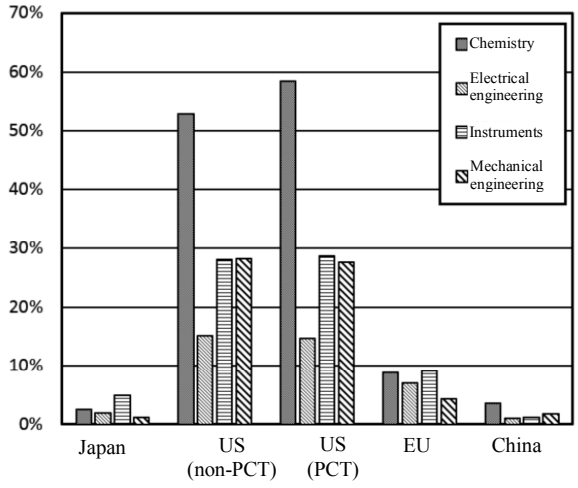
The figures for the EU include patent applications involving non-compliance with the unity of invention requirement, as well as patent applications failing to comply with the principle of "one independent claim in the same category" (Rule 43(2) of the Implementing Regulations of the European Patent Convention).

Table 4: Survey Results by Country and by Category

	Chemistry	Electrical engineering	Instruments	Mechanical engineering
JP	3%	2%	5%	1%
US (non-PCT)	53%	15%	28%	28%
US (PCT)	58%	15%	29%	28%
EU	9% (1%)	7% (1%)	9% (1%)	4% (1%)
CH	4%	1%	1%	2%

Note:The parenthesized figures for the EU are the percentage of applications causing a violation of Article 43(2) of the Implementing Regulations of the EPC.

Figure 1: Survey Results by Country and by Category (graph)



4. Differences in Determination of Unity of Invention between International Searching Authorities and National Patent Offices

Section 3 explains the result of the statistical survey concerning

examinations of unity of invention by the respective national or regional patent offices. Section 4 analyzes differences in determination of unity of invention by those patent offices in greater depth. For this analysis, we would like to explain the result of surveying 108 patent families covered by PCT applications filed from 2005 to 2007 (extended to Japan, the US, the EU, China, or Korea), in order to understand differences between the judgments about unity of invention by International Searching Authorities (ISA) in the PCT phase and the judgments made after entry into the national phase in respective countries. Since our survey was focused mainly on applications filed by Japanese enterprises, the PCT applications surveyed were chosen from those examined by the Japan Patent Office acting as the ISA. The file wrapper information of the patent families surveyed was obtained from the First Patent Committee of JIPA.

Regarding the applications examined in the countries other than the US (Japan, the EU, China, and Korea), there was no international search report (ISR) identifying lack of unity of invention. After entry into the national phase in each country, the applications receiving a notice of the reasons for rejection on the grounds of lack of unity of invention were as follows: one application (1%) in Japan, nine applications (8%) in the EU, four applications (4%) in China, and three applications (3%) in Korea. Thus, judgments about unity of invention generally match each other in the ISA's examinations and each national office's examinations.

On the other hand, the USPTO issued a notice of the reasons for rejection for 19 applications (18%) on the grounds of lack of unity of invention as a result of its own examinations, even though their ISR had not recognized lack of unity of invention. Compared with other countries, the US had a tendency to render judgments about unity of invention differing from ISA's judgments.

The most typical reason for determining non-compliance with the unity of invention requirement and issuing a notice of the reasons for rejection in the US is described as follows: independent claims falling under separate categories (e.g., a claim for products and a claim for a manufacturing method) do not involve any common STF based on citation of prior art documents (11 of 19 applications). Among those applications, given below are the case examples wherein the ISA and the USPTO made different judgments about unity of invention.

(1) Case where the USPTO judged that there was no STF by citing prior art documents determined to fall under Category "Y" in an ISR

Regarding an international application containing independent claims falling under separate categories

(International Application Number: PCT/JP2006/319573), the ISR determined that the cited documents were classified into Category "Y" (a category for documents to be cited to deny inventive step) and there was no mention of lack of unity of invention. However, in the process of the examination of a US application after entry into the US national phase (Application Number: 11/992646), the examiner determined that there was no STF by using the same documents as those cited in the ISR and issued a notice of the reasons for rejection on the grounds of lack of unity of invention in accordance with Rule 13 of the PCT Regulations.

(2) Case where unity of invention was judged based on non-PCT criteria

After an international application (International Application Number: PCT/JP2006/319572) entered the US national phase and was identified as a US application (Application Number: 12/ 067996), this US application received a notice of the reasons for rejection, without indication of any prior art documents and the applicable provision of the PCT Regulations. The applicant was informed that the claim for products and a manufacturing method should be divided to fulfill the unity of invention requirement based on MPEP 806.05, while this provision refers to the criteria for non-PCT applications.

(3) Case where no prior art documents were indicated

Regarding an international application containing independent claims falling under separate categories (International Application Number: PCT/JP2006/310780), the ISR determined that the prior art documents were classified into Category "A" (documents showing a technical background that can be used only for reference) and there was no mention of lack of unity of invention. However, a notice of the reasons for rejection was issued for a US application after entering the national phase (Application Number: 11/914843) on the grounds of lack of unity of invention, without indicating any prior art documents, while reference to Rule 13 of the PCT Regulations was made. In this decision, each of the independent claims was determined to be independent or distinct and to fall within a separate technology area and the examiner demonstrated a serious burden by insisting on the necessity of searching in different fields, etc. In fact, the examiner relied on the criteria for non-PCT applications in this case.

5. Why Are Many Patent Applications Rejected in the First Action on the Grounds of Lack of Unity of Invention in the US?

As explained in Section 3, the US has a higher percentage of issuing a notice of the reasons for rejection on the grounds of non-compliance with the

unity of invention requirement than the other countries. In this Section 5, we consider the causes of such tendency based on a comparison of the statutory provisions explained in Section 2 and the survey results described in Section 4. The conceivable causes that we inferred are listed as follows.

(i) Compared with the criteria enforced in the other countries, issuing a notice of the reasons for rejection is easier under the US criteria.
(ii) Since judgments about STFs in the US differ from those in the other countries or under the PCT, notices of the reasons for rejection due to lack of unity of invention in the US outnumber those in other countries.
(iii) Since the US maintains criteria different between PCT applications and non-PCT applications, US examiners are apt to mistakenly issue a notice of the reasons for rejection.
(iv) Other
Section 5 provides detailed explanations about these conceivable causes. As shown in Section 3, the US has a particularly high percentage of applications resulting in a finding of lack of unity of invention in the area of chemistry. The causes of this situation also are considered in Section 5.

5.1 Differences in Judgment Criteria between the US and Other Countries

As described in Section 2, the criteria for judging unity of invention for non-PCT applications in the US deviate significantly from the judgment criteria adopted in the other countries. We therefore consider that such difference in the judgment criteria constitutes one of the causes of a high percentage of issuing a notice of the reasons for rejection due to lack of unity of invention in the US.

As noted before, patent applications are to be rejected due to non-compliance with the unity of invention requirement under MPEP 803 when the claimed inventions are determined to be "independent or distinct" and expected to cause a "serious burden" on the examiner. We take a look at these two viewpoints based on differences in judgment criteria between the US and the other countries.

(1) Being independent or distinct

This viewpoint refers to the assessment to judge whether the claimed inventions are independent or distinct. Under MPEP 802.01, the term "independent" means that there is no disclosed relationship between the two or more inventions claimed. Understandably, there is no STF among two or more independent inventions. If such independent inventions are claimed in one application, no significant difference will arise in judgments about unity of invention between the US and the other countries. In the meantime, judging whether "distinct" or not seems to be based on

different ideas and criteria, while both the US and the other countries focus on the relationship between the claimed inventions in some way.

The countries other than the US judge unity of invention based on STFs, as explained in Section 2; if the claims falling under separate categories are determined to be related, they are to be treated as a single invention in the examination procedure in those countries. In contrast, the scope of inventions determined to be "distinct" is broader under the US criteria, whereby the claims falling under separate categories are readily recognized as being distinct.

Let us take an application claiming products and a manufacturing method as an example. In the countries other than the US, if the claimed manufacturing method is determined appropriate for the manufacture of the claimed products, those manufacturing method and products will be determined to be related to each other and unity of invention will be acknowledged. In the US, if the invention claimed for the products can be manufactured by any method other the claimed manufacturing method, the claimed products and manufacturing method will be determined to be distinct based on the patterns of "related invention" listed in MPEP 806.05 (MPEP 806.05(f)). In reality, a situation where the claimed manufacturing method is the only way to manufacture the claimed products is very rare. In most cases, therefore, the inventions of products and a manufacturing method in one application are considered to be independent or distinct under the US criteria.

In this way, the claimed inventions examined under the US criteria are more likely to be recognized as being independent or distinct, compared with the assessment in the other countries.

(2) Serious burden

This viewpoint refers to the assessment to judge whether or not there would be a "serious burden" in the examination process. No similar judgment criteria are established in the countries other than the US. This rule seems to allow US examiners to easily demonstrate that there would be a serious burden. Below are the reasons for such inference.

As explained in Section 2, MPEP 808.02 provides guidelines for applying this rule. If multiple claims in one application involve different patent categories (separate classification), separate technology areas (separate status in the art), or different scopes of prior art search (separate field of search), they are considered to cause a serious burden on the examiner.

If the claimed inventions fall under different categories, they will be readily recognized as being distinct, as explained in (1) above. In this event, the requirements for demonstrating a serious burden also will be readily satisfied. For example, even when a claim for products and a claim for a

manufacturing method are closely related to each other, these claims are, in general, to be classified into separate patent categories. Therefore, the examiner has only to show separate classification, and then the requirement for a serious burden can be readily satisfied.

With regard to at least the "separate field of search" requirement, it is considered possible to insist on the necessity to examine a different scope of search merely because one application involves separate claims. This means that a "separate field of search" is applicable based on each examiner's subjectivity. In other words, if the examiner judges that there would be some burden in examination, the examiner can conclude that it would be a serious burden. In this way, it is easy for examiners to apply the serious burden criterion.

Owing to these criteria which are readily applicable based on either "independent or distinct" or "serious burden," patent applications examined in the US are apt to be rejected in the first action on the grounds of non-compliance with the unity of invention requirement.

If these judgment criteria peculiar to the US impose a heavier burden on applicants in the US national phase alone, such criteria must be corrected for the sake of patent system harmonization. As with the other countries, the US should introduce the assessment of unity of invention based on STFs in conformity with the PCT criteria and abolish the criteria allowing for subjective and discretionary operation by examiners. We have already proposed this reform in conferences discussing patent system harmonization and on other occasions, and the proposal has gained some support by associations organized by patent applicants or owners, among others. The First International Affairs Committee will continue to advocate this proposal on appropriate occasions.

With the full-scale launch of the Cooperative Patent Classification (CPC) system in the US from FY2015, the patent classification used to establish a serious burden has been shifted from the United States Patent Classification (USPC) to the CPC system. We are observing how this changeover will affect the percentage of issuing a notice of the reasons for rejection on the grounds of lack of unity of invention in the US.

5.2 Differences in Practical Guidelines for Judging STFs

As described before, US applications filed through the PCT route are supposed to undergo a process of judging unity of invention based on the PCT criteria in principle, namely, based on the criteria for judging STFs, before commencement of substantive examination at the USPTO. Since some applications may be rejected on the grounds of non-compliance with the unity of invention requirement in this process, the number of applications to

be covered by substantive examination can be reduced in advance. To enforce this operation, the examiner is required to demonstrate that there is no STF for the inventions claimed in the application being examined.

The practical procedure by examiners starts with the assessment of an STF or STFs in the claims in comparison with the prior art mentioned in the International Search Report (ISR). Since the criteria for judging STFs are strict in the US, we inferred that such strict criteria contributed to a high percentage of rejection notices on the grounds of lack of unity of invention in the US.

The survey as described in Section 4 discovered 16 PCT applications resulting in a finding of lack of unity of invention in the US national phase whereas their ISR had not recognized lack of unity of invention. As a result of scrutinizing these 16 applications, we found that three of them had received a notice of the reasons for rejection on the grounds of lack of unity of invention, based on the citation of the documents classified into Category "X" (a category for documents to be cited to deny novelty) in their ISR to demonstrate that there was no STF. We also found that four of the 16 applications had received a notice of the reasons for rejection on the grounds of lack of unity of invention, based on the citation of the documents classified into Category "Y" to demonstrate that there was no STF. Each of the three applications first mentioned contained multiple independent claims, but at least one of those claims was determined to lack novelty in their ISR. It is therefore not surprising that even though the ISR had stated that there was no STF, the judgment made in the US national phase is considered to match the PCT criteria in this respect. With regard to the four applications mentioned above, the notice of the reasons for rejection based on lack of unity of invention describes the reasons for judging that there was no STF. In this sense, the US examination of each of those four applications is considered to match the PCT criteria. In summary, while judgments about STFs in the US meet the PCT criteria in general, the practical guidelines for making such judgments in the US are more stringent than those in the other countries. This is considered to raise the percentage of issuing a notice of the reasons for rejection due to lack of unity of invention in the US. While such notices state the reasons for judging that there was no STF, we discovered that those statements are detailed in some cases and simplified in other cases. To ascertain whether the reasons for such judgments are sufficiently explained or not, we are going to continue our observations and considerations in this respect.

We need to encourage efforts for patent system harmonization in terms of judgments about STFs in the US. At the same time, however, we would like to remind applicants of the high likelihood of receiving a notice of the

reasons for rejection on the grounds of lack of unity of invention in the US when documents falling under Category X or Category Y are cited in the ISR. With this in mind, applicants are recommended to consider submitting a preliminary amendment in advance to modify a claim appropriately according to circumstances.

5.3 Why Many Patent Applications in the Field of Chemistry Are Rejected in the First Action Due to Lack of Unity of Invention

As explained in Section 3, the percentage of applications resulting in a finding of lack of unity of invention (i.e., the restriction requirement ratio in the US) is remarkably high in the area of chemistry. In this subsection, we look into characteristics identified in patent applications in the area of chemistry.

(1) Composition of claims

As a result of analyzing types of restriction, frequently used reasons for requiring restriction are listed as follows in descending order: MPEP 806.05(h) (Product and Process of Using) accounted for 62%, MPEP 806.05(j) (Related Products; Related Processes) for 35%, and MPEP 806.06 (Independent Inventions) for 15%. Two or more types of the foregoing were mentioned at the same time in some cases. A finding of lack of unity of invention relies on these provisions probably because applications filed in the area of chemistry are usually drafted in such a form to claim a new substance as the first invention and to claim a method for synthesizing or using this new substance or a composition of matter formed by mixing the new substance and other ingredients as the second and subsequent inventions. Such composition of claims is apt to receive a judgment acknowledging unity of invention in the surveyed countries other than the US. On the contrary, the US tends to determine that such claims are “independent or distinct” and would potentially cause a “serious burden.”

(2) Restriction requirement ratios by art unit

Subsequently, our analysis focused on examinations in the area of chemistry by the respective units of the USPTO. The area of chemistry is broadly divided into the chemical field and the medical and pharmaceutical field. We reviewed the file wrappers for each of the patent families chosen, constituting 108 applications in total. These 108 applications include 12 applications in the chemical field and 11 applications in the medical and pharmaceutical field, for which a notice of the reasons for rejection was issued on the grounds of lack of unity of invention in the US. The units in charge of the examinations of those applications in the USPTO are as follows: five applications in the

chemical field and 11 applications in the medical and pharmaceutical field by Art Unit 1600 (Biotechnology and Organic Chemistry), and seven applications in the chemical field and zero in the medical and pharmaceutical field by Art Unit 1700 (Chemical and Materials Engineering). In general, it seems that Art Unit 1600 is responsible for examinations in the medical and pharmaceutical field and that Art Unit 1700 is responsible for examinations in the chemical field.

According to "PATENTLYO," a website launched on June 15, 2010 to offer information on published patent applications that have been disposed of (http: //patentlyo.com/patent/2010/06/likelihood-of-office-action-rejections.html), the restriction requirement ratio is 54% in Art Unit 1600 and 21% in Art Unit 1700. In other words, a higher restriction requirement ratio is found in the chemical field than in the medical and pharmaceutical field.

(3) Characteristics in the medical and pharmaceutical field

Of the 108 patent families reviewed as described in Section 3, we scrutinized the patent families classified in the medical and pharmaceutical field. The applications scrutinized here are seven patent families filed through the PCT route and subsequently entering the US national phase, involving the same compositions of claims in the PCT phase and the US national phase, and resulting in the USPTO's finding of lack of unity of invention while the ISR acknowledged unity of invention in the PCT phase.

Why does the medical and pharmaceutical field show a remarkably high restriction requirement ratio in the area of chemistry? We presume that this situation depends on whether inventions of diagnostic or therapeutic methods are claimed or not, since diagnostic and therapeutic methods are not eligible for patent protection in the countries other than the US. In other words, such a situation is considered to be caused by the difference in the scope of patentable inventions.

Two of the seven surveyed patent families in the medical and pharmaceutical field received a notice of the reasons for rejection due to lack of unity of invention recognized in connection with diagnostic or therapeutic methods. The rejection notice for each of those two patent families refers separately to the claimed invention for products and the claimed invention for a diagnostic or therapeutic method using the products.

International Application Number PCT/JP2006/311073 (US Application Number: 11/916356) mentioned before is considered in more detail below. In the examination process in the US, the claimed invention for the products was determined to lack novelty based on cited references which had not been mentioned in the ISR. As a result, the claimed invention for a diagnostic or

therapeutic method in a separate category was determined to lack unity of invention on the grounds that there was no STF. Looking at the patent application bearing the International Application Number of PCT/JP2006/319912 (US Application Number: 11/992817), a therapeutic (preventive) drug was claimed in the PCT phase and the subject matter of the claim was changed to a therapeutic (preventive) method when entering the US national phase. However, this application was determined to fail to fall under any of the specified categories (37 CFR 1.475) and resulted in a finding of lack of unity of invention in the US examination, without citing any references.

While the propriety of a judgment by a US examiner can be controversial, this is a problem peculiar to the medical and pharmaceutical field. Diagnostic or therapeutic methods are not eligible for patent protection in the countries other than the US. If a claim contains an invention for a diagnostic or therapeutic method when entering the US national phase, US examiners seem to have a tendency to recognize lack of unity of invention. Therefore, the difference in the scope of patent protection between the US and the other countries is presumed to be a major factor leading to a high restriction requirement ratio in the medical and pharmaceutical field than in other fields in the area of chemistry.

(4) Summary of Subsection 5.4

The area of chemistry as a whole tends to show a high restriction requirement ratio, especially in the medical and pharmaceutical field.

Since our survey this time covers only a limited number of patent applications, we are going to continue to observe and consider this issue.

5.4 Coexistence of PCT Criteria and Non-PCT Criteria

As explained in the preceding sections, the US adopts separate criteria for PCT applications and for non-PCT applications to judge unity of invention. US examiners are therefore forced to use different criteria according to the filing route, even though their judgment is made for the same claim within the same nation. This may sometimes lead to their misunderstanding or confusion when adopting the judgment criteria, and some applications may mistakenly result in a finding of lack of unity of invention which should otherwise be avoided.

As a result of analyzing the details of 16 applications resulting in a finding of unity of invention, we found that two of them were examined and judged under the non-PCT criteria while they should have been controlled by the PCT criteria.

While we cannot conclude at present that such situations raise the percentage of recognizing lack of unity of invention in the US, erroneous judgments are never acceptable to applicants. If an applicant faces such

misjudgments, it would be worth considering traversing the examiner's decision or action.

Needless to say, patent systems must be properly operated in such a way as not to cause incorrect judgments. More importantly, however, such misjudgments as explained here would never occur if the PCT criteria alone were used as the standard for assessing unity of invention. We therefore intend to advocate proper operation of patent systems, as well as integrated adoption of the PCT criteria as the standard for judging unity of invention.

5.5 Other Conceivable Causes

As illustrated in Section 2, this document is based on the assumption that the concept of a "finding of lack of unity of invention" when used with reference to the US includes a requirement for restriction or election of species. The provisions concerning a restriction requirement refer to unity of invention between the claimed species, which is intended to require the applicant to elect a single group (species). On the other hand, an election of species requirement is related to a patent application for a single generic claim covering multiple species and this is intended to require the applicant to elect a species when such a generic claim is not patentable. Since each species corresponds to a specific embodiment in general, the applicant usually elects one embodiment accompanied by one species, resulting in the election of the claim corresponding to the elected embodiment. Determination of unity of invention in the countries other than the US is a process of assessing unity of invention between the claims in one application, which resembles the concept of restriction between the claims in the US. However, there is no concept equivalent to election of species in the assessment of unity of invention in the countries other than the US. After the applicant elects one species in response to an election of species recruitment, its claim may eventually be accepted as one application if the generic claim withdrawn is considered. If, however, the claim is determined not to cover one species, the applicant will need to divide the application. The burden on the applicant in this event is similar to the burden in case of a restriction requirement. This is why we consider that an election of species requirement is similar to a finding of non-compliance with the unity of invention requirement.

According to our survey, the percentage of rejection notices due to lack of unity of invention involving an election of species requirement only was 14% in the area of chemistry, 6% in the area of electrical engineering, 12% in the area of instruments, and 10% in the area of mechanical engineering. These figures show that the concept of election of species contributes to raising the total percentage of issuing a notice of the

reasons for rejection due to lack of unity of invention in the US.

Another conceivable factor contributing to such a high ratio of rejection notices is the trend toward timely patent prosecution in the US. The USPTO is promoting a strategy to achieve timely examination with specified goals. When former Director David J. Kappos took office in the USPTO, the 2010-2015 Strategic Plan was established to enhance patent quality and timeliness. Under this plan, examiners were encouraged to identify patentable subject matter early and strive for "compact prosecution" to optimize patent pendency.2) This plan set out the target time periods for patent prosecution practices to be followed by each examiner for each application. Such targets require examiners to complete the whole process from search through examination to first office action within this time constraint. US examiners therefore seem to prefer to narrow the scope of examination with the intention of reducing the time spent for reviewing each application.

Furthermore, there are some opinions that the USPTO's patent examiner count system, i.e., the performance evaluation system for examiners, contributes to a high percentage of rejection notices on the grounds of lack of unity of invention. It is a fact that examiners are supposed to be granted reward points according to the number of applications processed, and this reward point system may motivate examiners to process as many applications as possible. Therefore, it is highly likely that US examiners are eager to issue a rejection notice based on non-compliance with the unity of invention requirement.

6. Conclusion

In this survey, we compared major countries' systems concerning unity of invention and investigated trends in their judgments in patent prosecution. The survey showed that the US is peculiar in terms of the unity of invention scheme, as well as in terms of the percentage of issuing a notice of the reasons for rejection on the grounds of lack of unity of invention. With a focus on the US, which has a particularly high percentage of rejection notices in the first action, we considered its reasons and identified the key points in light of patent system harmonization.

Regarding non-PCT applications in the US, we ascertained that they tend to face a notice of the reasons for rejection due to lack of unity of invention primarily because the US examination criteria are prone to such judgments. Regarding PCT applications in the US, US statutory provisions concerning unity of invention conform to the PCT criteria, as is the case with other major countries. Nevertheless, we found a strong tendency of willingly issuing a notice of the reasons for rejection on the grounds of lack of unity of invention, while conforming to the PCT-compatible criteria.

When asking the US to harmonize

the patent system in terms of unity of invention, it is not enough to call for alignment with the other countries' criteria, but it is also important to ask for harmonization in terms of operation of the criteria in parallel.

From the standpoint of applicants, the decision to issue a notice of the reasons for rejection due to lack of unity of invention in the US national phase appears to have been somewhat unsatisfactory, but many of those applicants may not have bothered to object. Going forward, however, we recommend applicants to raise objections when the examiner's decision does not meet the criteria, recognizing the judgment criteria in the US and their peculiarity. We expect that such responses by applicants will help improve the level of individual examiners in the US. If their examination quality is improved, the number of applications that are easily rejected on the grounds of lack of unity of invention is expected to be reduced, which will surely be advantageous for applicants. We hope the survey outlined in this document will help promote the harmonization of patent systems among the IP5 nations in terms of determination of unity of invention, and help JIPA members develop an understanding of the criteria concerning unity of invention of the IP5 nations.

Notes:

1)"Results of the Seventh Meeting of the IP5 Heads of Office Held in Busan, ROK," News Release dated June 6, 2014 (published in English on April 18, 2014) http://www.meti.go.jp/english/press/index.html (accessed and confirmed in 2016)

2)「米国特許商標庁の改革に伴う審査環境の変化とそれに対応した実務」(知財管理(IP Management) Vol. 61, No. 8, 2011)

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