

# 1 Desirable Border-Enforcement System Against Intellectual Property Infringing Goods

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*This research was based mainly on the following two processes. Firstly, the Committee on Border Measures Against Counterfeits Through Application of the Unfair Competition Prevention discussed a guide for determining violation of the Unfair Competition Prevention Law for import suspension. The guide will be used as a reference in the preparation of the written opinion of the Minister of Economy, Trade and Industry as is required upon seeking import suspension. It will also be used for the provision of the opinion of the Minister of Economy, Trade and Industry when such an opinion is sought in the infringement-determination procedure in the system of border enforcement against goods that constitute the acts referred to in Article 2(1)(i) to (iii) of the Unfair Competition Prevention Law, which was introduced by the amendment of the Customs Tariff Law on March 1, 2006. Secondly, the Working Group for Studying Japan's Desirable Border-Enforcement System Against IP Infringing Goods was set up to gather information to contribute to the study of Japan's desirable border-enforcement system. This was conducted by identifying the current status and challenges of Japan's border-enforcement system and investigating overseas border-enforcement systems and frameworks. Furthermore, discussions were held to make contributions to upgrading the Japanese border-enforcement system against intellectual property infringing goods.*

## **I Committee on Border Measures Against Counterfeits Through Application of the Unfair Competition Prevention Law**

The Committee on Border Measures Against Counterfeits Through Application of the Unfair Competition Prevention compiled a guide for determining violation of the Unfair Competition Prevention Law for import suspension. The guide will be used as a reference in the preparation of the written opinion of the Minister of Economy, Trade and Industry as is required upon seeking import suspension, the infringement-determination procedure of Customs, and the provision of the opinion of the Minister of Economy, Trade and Industry when such an opinion is sought by the Director-General of Customs in the infringement-determination procedure, in the system of border enforcement against goods that constitute the acts referred to in Article 2(1)(i) to (iii) of the Unfair Competition Prevention Law. The committee created the guide by investigating and analyzing past court cases related to the Unfair Competition Prevention Law, particularly those that were likely to become subject to import suspension, extracting the requirements and ideas for determining the acts referred to in Article 2(1)(i) to (iii) of the Unfair Competition Prevention Law from these cases, and holding concrete discussions on each of them.

## **1 Border-enforcement system against goods that violate the Unfair Competition Prevention Law**

Unlike registration-based intellectual property (IP) such as patents, there is no certification of right that is equivalent to a registration certificate in the border-enforcement system against goods that violate the Unfair Competition Prevention Law. Therefore, when seeking import suspension from Customs, one must furnish Customs with the opinion of the Minister of Economy, Trade and Industry on the following matters to prove his/her rights: i) the fact that the indication of goods or business pertaining to the party holding the right to seek import suspension is widely recognized by consumers nationwide (Article 2(1)(i) of the Unfair Competition Prevention Law); ii) the fact that the indication of goods or business pertaining to the party holding the right to seek import suspension is famous (Article 2(1)(ii) of the Unfair Competition Prevention Law); and/or iii) the fact that the configuration of the goods pertaining to the party holding the right to seek import suspension is not indispensable for ensuring the function of the goods, and three years have yet to elapse from the date on which the goods were first sold in Japan (Article 2(1)(iii) of the Unfair Competition Prevention Law). Therefore, the party seeking import suspension needs to request and acquire from the Minister of Economy, Trade and Industry the written opinion before seeking

import suspension from Customs.

Incidentally, there is a system in which the Director-General of Customs can seek the opinion of the Japan Patent Office Commissioner in the procedure for determination on patent, utility model, or design right. Therefore, an equivalent procedure was introduced to enable the Director-General of Customs to refer to the opinion of the Minister of Economy, Trade and Industry on whether or not certain goods constitute any of the acts listed in Article 2(1)(i) to (iii) of the Unfair Competition Prevention Law, in the infringement-determination procedure when the application for import suspension is accepted by Customs and the allegedly infringing goods are prevented from entering Japan.

## **2 Goods violating the Unfair Competition Prevention Law subject to import suspension**

### **(1) Goods that constitute acts of Article 2(1)(i) (acts that cause confusion with well-known indications of goods or business) or Article 2(1)(ii) (misappropriation of famous indications of goods or business) of the Unfair Competition Prevention Law**

#### **(i) Another party's indication of goods or business**

The committee identified the following as important factors and discussed them: i) another party; ii) goods; iii) business; and iv) indication of goods or business.

#### **(ii) Widely recognized among consumers (well-known status)**

The committee identified the following as important factors and discussed them: i) consumers; ii) wide recognition; iii) areas where the indication is well-known; and iv) determination of well-known status.

#### **(iii) Identical or similar to an indication of goods or business**

The committee discussed the following aspects: i) in the concept of "similar" in cases including the Morimitsu case (Tokyo District Court judgment of August 3, 1981) and in the concept of similarity of trademarks under the Trademark Law, identicalness or similarity is determined comprehensively by independently observing the "sound," "concept," and "appearance"; ii) in the Manpower case (Supreme Court judgment of October 7, 1983), "similarity" was determined based on similarity as a whole; and iii) in the Vogue case (Tokyo District Court

judgment of July 2, 2004), the approach taken to compare the indications of the plaintiff and the defendant was to extract the substantial part of the indication by eliminating the parts that are "quality indication," the "article to the noun," "common noun," and "commonly-used trademark," which were the differing parts of the two indications.

#### **(iv) Causing confusion with another party's goods or business (confusion)**

The committee identified the following as important factors and discussed them: i) threat of causing confusion; and ii) confusion in the narrow sense and in the broad sense.

#### **(v) Exclusion from application (Article 19(1)(i) to (iv) of the law)**

The committee identified the following as important factors and discussed them: i) common name for goods or services; ii) goods made from grapes or using grapes as an ingredient; iii) indication of goods or business that is commonly used for identical or similar goods or business; iv) using in a normally used manner; v) using one's own name without wrongful purpose; vi) using another party's indication of goods or business before such indication became well-known or famous; and vii) using an indication that does not correspond to an indication of goods or business.

#### **(vi) Another party's famous indication of goods or business**

The committee identified the following as important factors and discussed them: i) "famous;" ii) fame "nationwide"; and iii) whether or not the act corresponds to dilution or free-riding.

### **(2) Goods that constitute acts of Article 2(1)(iii) (imitation of the configuration of goods)**

#### **(i) Purpose of legislation**

The provision of Article 2(1)(iii) of the Unfair Competition Prevention Law was introduced upon a sweeping revision of the law in 1993. Although it is not expressed in the language of the provision, the prevalent theory and court judgments construe it as a provision for "protecting the interests of the prior developer," considering the purpose and the course of development of the legislation.

#### **(ii) Claims and evidence of the plaintiff**

The committee identified the following as important factors and discussed them: i) "configuration of the goods"; ii) "another party" in Article 2(1)(iii) of the Unfair Competition Prevention Law; iii) exclusion of configuration

that is indispensable for ensuring the function of the goods; iv) the term of protection; v) the defendant's act of assignment, etc.; vi) imitation; and vii) infringement or a threat of infringement of the plaintiff's business interests.

(iii) **Claims and evidence of the defendant**

The committee identified the following as important factors and discussed them: i) denial that the configuration of the goods is identical to the configuration of the plaintiff's goods; ii) exclusion of a configuration that is indispensable for ensuring the function of the goods; iii) denial of the defendant's act of assigning, delivering, displaying for the purpose of assignment or delivery, exporting, or importing the goods; iv) denial of imitation; v) defense that three years have elapsed from the day the goods were first sold in Japan; vi) denial of infringement or a threat of infringement of the plaintiff's business interests; and vii) reasons for exclusion from application, such as acquisition in good faith and absent gross negligence, or parallel import of the genuine goods.

**3 Acts in Article 2(1)(i) (acts that cause confusion with well-known indications of goods or business), Article 2(1)(ii) (misappropriation of famous indications of goods or business), and Article 2(1)(iii) (imitation of the configuration of goods) of the Unfair Competition Prevention Law that serve as the basis for import prohibition**

**(1) Acts in Article 2(1)(i) (acts that cause confusion with well-known indications of goods or business)**

(i) **Related provisions**

Related provisions are: i) Article 2(1)(i) (acts that cause confusion with well-known indications of goods or business); ii) Article 2(2) (definition: a trademark); iii) Article 2(3) (definition: a mark); iv) Article 3(1) (right to seek suspension of an act of unfair competition); v) Article 19(1)(i) (exclusion from application: common names and commonly used indications); vi) Article 19(1)(ii) (exclusion from application: one's own name); and vii) Article 19(1)(iii) (exclusion from application: use before the indication became well-known).

(ii) **Type of acts**

If an act creates confusion with another party's goods or business by importing goods that use an indication that is well-known among consumers as said party's indication of goods or business, it would constitute an act of unfair

competition (acts that cause confusion with well-known indications of goods or business).

Such acts are stipulated so as to protect consumers from confusion as to the source of goods or business. However, as long as the threat of confusion exists, these acts also have an indirect effect of prohibiting free-riding on another party's achievement of making the indication of goods or business widely known to consumers through marketing efforts and capital investment (acquisition of a well-known status).

**(2) Acts in Article 2(1)(ii) (misappropriation of famous indications of goods or business) of the Unfair Competition Prevention Law**

(i) **Related provisions**

Related provisions are: i) Article 2(1)(ii) (misappropriation of famous indications of goods or business); ii) Article 2(2) (definition: a trademark); iii) Article 2(3) (definition: a mark); iv) Article 3(1) (right to seek suspension of an act of unfair competition); v) Article 19(1)(i) (exclusion from application: common names and commonly used indications); vi) Article 19(1)(ii) (exclusion from application: one's own name); and vii) Article 19(1)(iii) (exclusion from application: use before the indication became well-known).

(ii) **Type of acts**

If an act of importing goods for which another party's famous indication of goods or business is wrongfully used as one's own indication, it constitutes an act of unfair competition (misappropriation of famous indications of goods or business).

The import of goods using a widely recognized indication of goods also constitutes an act of unfair competition in the case of acts of causing confusion. However, such an act does not constitute an act of unfair competition if it does not cause misunderstanding or confusion that the goods are identical to the genuine goods. In this respect, in the case of an unauthorized use of a famous indication of goods or business, there is a risk that the unauthorized user is free-riding on the social reputation built by the brand, and diluting the value as well as polluting the social reputation of the brand, even if the use does not cause misunderstanding or confusion.

Therefore, misappropriation of famous indications of goods or business is stipulated as an act of unfair competition without requiring the presence of confusion.

### **(3) Acts in Article 2(1)(iii) (imitation of the configuration of goods) of the Unfair Competition Prevention Law**

#### **(i) Related provisions**

Related provisions are: i) Article 2(1)(iii) (imitation of the configuration of goods); ii) Article 2(4) (definition: configuration of goods); iii) Article 2(5) (definition: imitation); iv) Article 3(1) (right to seek suspension of an act of unfair competition); v) Article 19(1)(v)(a) (exclusion from application: goods for which three years have elapsed from the day they were first sold in Japan); and vi) Article 19(1)(v)(b) (exclusion from application: acquisition in good faith and absent gross negligence).

#### **(ii) Type of acts**

Acts of importing goods that imitate the configuration of another party's goods constitute acts of unfair competition.

The basic idea of stipulating these acts as acts of unfair competition is to restrain imitation for three years as a period for collecting the considerable amount of costs that the prior developer of the goods had paid in devising a characteristic configuration of goods, conducting trial production, manufacturing the goods, advertising the goods, and placing them on the market—in short, it is a protection of the prior developer's interests.

Counterfeits are regulated by the provision on acts that cause confusion with well-known indications and that on misappropriation of famous indications. However, these provisions premise that the indication of the genuine goods has been spread among consumers and is made well-known or famous, so they do not provide sufficient protection for goods that have short life cycles, such as clothes, and goods that are in large variety, such as toys, which sometimes disappear from the market before the indication of the goods become well-known or famous, making it difficult to collect the costs required for the manufacture and sales when counterfeits appear. Therefore, there is significance in regulating acts of assigning goods that imitate the configuration of another party's goods as acts of unfair competition for a specific period (three years) after the goods were first sold, irrespective of whether the indication has become well-known or famous.

### **4 Relationship between the Minister of Economy, Trade and Industry and Each Requirement**

#### **(1) Written opinion of the Minister of Economy Trade and Industry to be furnished when a party holding the right to seek suspension of an act of unfair competition seeks a determination procedure from the Director-General of Customs (Article 21-2 of the Customs Tariff Law)**

The committee will extract 16 requirements that are considered to be important for determining whether goods violate the Unfair Competition Prevention Law for suspending import. When preparing a written opinion, the Minister of Economy, Trade and Industry will determine the following based on those of the 16 requirements that he/she considers necessary: i) the indication of goods or business pertaining to the party holding the right to seek suspension of an act of unfair competition is widely recognized among consumers nationwide (Article 2(1)(i) of the Unfair Competition Prevention Law); ii) the indication of goods or business pertaining to the party holding the right to seek suspension of an act of unfair competition is famous (Article 2(1)(ii) of the Unfair Competition Prevention Law); and (iii) the configuration of the goods pertaining to the party holding the right to seek suspension of an act of unfair competition is not indispensable for ensuring the function of the goods, and three years have yet to elapse from the date on which the goods were first sold in Japan (Article 2(1)(iii) of the Unfair Competition Prevention Law).

#### **(2) Opinion of the Minister of Economy, Trade and Industry sought by the Director-General of Customs, as a reference material, on whether or not certain goods are infringing goods in the infringement-determination procedure (Article 21-4-2 of the Customs Tariff Law)**

When preparing an opinion, the Minister of Economy, Trade and Industry will determine the following based on those of the 16 requirements that are necessary: i) whether or not the imported goods correspond to goods that constitute the acts referred to in Article 2(1)(i) of the Unfair Competition Prevention Law; ii) whether or not the imported goods correspond to goods that constitute the acts referred to in Article 2(1)(ii) of the Unfair Competition Prevention Law; and iii) whether or not the

imported goods correspond to goods that constitute the acts referred to in Article 2(1)(iii) of the Unfair Competition Prevention Law.

## 5 Guide for determining violation of the Unfair Competition Prevention Law for import suspension

The committee compiled a guide for determining violation of the Unfair Competition Prevention Law for import suspension, based on its examination and discussions. The guide will be used as a reference in the following procedures between the Ministry of Economy, Trade and Industry and Customs: i) the preparation of the written opinion of the Minister of Economy, Trade and Industry; ii) the acceptance of an application for import suspension; iii) the infringement-determination procedure of Customs; and iv) the provision of the opinion of the Minister of Economy, Trade and Industry when such an opinion is sought by the Director-General of Customs.

## II Working Group for Studying Japan's Desirable Border-Enforcement System against IP Infringing Goods

The Working Group for Studying Japan's Desirable Border-Enforcement System against IP Infringing Goods gained an understanding of the current status and challenges of Japan's border-enforcement system against IP infringing goods, which has been continuously developed through revisions of the Customs Tariff Law and increasing its effectiveness in recent years, in light of the industrial views, viewpoints of litigation practice, and international agreements including GATT and the TRIPS Agreement. Based on this, the working group investigated and organized information on the current status of the frameworks of border-enforcement systems against IP infringing goods in foreign countries. In this way, it gathered information that will contribute to future study of Japan's desirable border-enforcement system against IP infringing goods.

## 1 Relationships between Japan's border-enforcement system and international agreements

### (1) Relationships between Japan's border measures and the Agreement Establishing the World Trade Organization (WTO Agreement) and other agreements

(i) Organizations concerning border measures stipulated in the TRIPS Agreement and the corresponding organizations in Japan and other countries

TRIPS Agreement	Japan	EU	USA
Authorities having the power to decide suspension of release by customs authorities (Article 51: competent authorities)	Customs (final decision made by Director-General of Customs [capable of seeking an opinion])	Customs	International Trade Commission (ITC)
Organization implementing the proceedings leading to a decision on the merits of the case (Article 55: duly empowered authority)	Customs	Court	ITC
Execution authority (Article 51: customs authorities)	Customs	Customs	Customs

(ii) Desirable points to be reviewed in terms of compliance with WTO procedures

At the time of conclusion of the TRIPS Agreement, the systems for seeking import suspension existed only for copyright and trademark in Japan, so compliance had been achieved in the absence of the systems for seeking import suspension based on patents and design rights or based on the Unfair Competition Prevention Law. Recently, however, there has been an industrial demand that the following matters be reviewed regarding appropriate handling of IP infringing goods upon export and import from the viewpoint of achieving compliance of these systems for seeking import suspension and the TRIPS Agreement: i) making of decisions by the Director-General of Customs to accept applications for import suspension; ii) granting of temporary relief by the Director-General of Customs; iii) infringement-determination procedure by the Director-General of Customs; iv) evidence-collection procedure; v) defense by the alleged infringer; and vi) status of

the applicant of import suspension.

## **(2) Border-enforcement system against IP infringing imported goods stipulated in Article 21 of the Customs Tariff Law and its compliance with the WTO Agreement**

The compliance of the border-enforcement system against goods that infringe IP rights including patents and registered trademarks, which is stipulated in Article 21 onward of the Japanese Customs Tariff Law and related administrative regulations, with the relevant treaties in the Annexes of the WTO Agreement was examined, and the following were found:

(i) In the Japanese border-enforcement system, suspension of release and decision on the merits of the case are integrated, and this differs from the design of the system assumed by the TRIPS Agreement.

(ii) As a result of such peculiarity, there are procedural differences between the border-enforcement system and the IP infringement litigation, and the system is considerably disadvantageous for imported goods. Therefore, the system does not comply with Article III:4 of the General Agreement on Tariffs and Trade (GATT), and cannot be justified by Article XX:(d) of GATT. It is also very likely that the system does not comply with the general principles of IP right enforcement stipulated in Part III, Section 1 of the TRIPS Agreement.

(iii) However, if Japan's border-enforcement system is regarded as a measure for suspension of release, generally high compliance could be achieved with Part III, Section 4 of the TRIPS Agreement.

(iv) A number of notable non-compliant points could be found with respect to Part III, Section 2 of the TRIPS Agreement. It cannot be denied that there are deficiencies in the border-enforcement system against the related provisions of the TRIPS Agreement, particularly in terms of the procedural rules concerning the offer and handling of information and evidence.

## **2 Challenges of Japan's border-enforcement system and prospects for a desirable system**

### **(1) Evaluation of the current border-enforcement system and challenges for future discussion**

(i) Evaluation of the current border-enforcement system  
Considering that other parts of Asia are

inundated with counterfeits and pirated copies produced by unidentified parties, Japan's current border-enforcement system is an effective border measure against immediately obvious counterfeits and pirated copies (for which it is difficult for importers to defend). It is hoped that the system will be further improved into a more accessible system for right holders in the future.

#### **(ii) Challenges for future discussion**

i) It is necessary to discuss establishment of a function to stop infringing goods at the border by way of hearing the arguments of both parties under due process and promptly determining the infringement status and the validity of the right, through introduction of another system (e.g., use of courts) apart from the current border-enforcement system.

ii) To improve the current system, the following need to be discussed while also bearing in mind introduction of the system referred to in i): (a) reviewing the customs-release system; (b) increasing the types of IP rights subject to border enforcement; (c) and reducing the burden on the right holders.

#### **(iii) Conclusion**

Apart from the current border-enforcement system against immediately obvious counterfeits and pirated copies, it is essential to introduce another system for stopping infringing goods at the border by way of determining the IP right infringement status. Such a system should be designed so as not to appear unfair for importers, while consideration should be given to using the existing organizations as much as possible.

## **(2) Needs and the feasibility of introducing an ITC-style quasi-judicial system: from a practical viewpoint**

### **(i) Introduction**

The current border-enforcement system against patent-infringing products determines the infringement status by premising the validity of the patent right, so it differs from the court's process in a patent infringement case. Therefore, the procedural protection for importers is insufficient, and when a retaliation measure is taken in the country of the import supplier in line with the use of the system, the use of the system involves a lot of difficulties.

It is impossible in terms of human and material resources to have Customs also determine the validity of patent right under the current border-enforcement system, so it would be possible to establish an ITC-style quasi-judicial organization that will take the role of

determining the patent validity. However, considering the current fiscal conditions, it would not be possible to enact such a system into law unless the need for the system becomes very clear.

In view of this point, the need and the feasibility of introducing an ITC-style quasi-judicial system were examined.

(ii) **Problems in the current system and the direction of improvement**

i) One of the problems in the current system is that the system may appear to be unfair in the eyes of not only importers, but also overseas manufacturers producing the imported goods, since it is a common concept in the world that determination of patent validity is indispensable for determining the patent infringement status under the current law. Therefore, as exemplified by the dispute between Matsushita Electric Industrial Co. Ltd. and LG Electronics Inc. concerning plasma display panel patents, there is a risk that the system would give rise to a political problem such as an overseas manufacturer seeking a retaliation measure in its own country against a patentee who sought import suspension.

ii) A possible direction of improvement would be to provide the importers a means for disputing over patent validity under the current system, but since it would impose an excessive burden on the human and material resources to have Customs even determine the patent validity, this would not be a reasonable approach. It is necessary to consider determination of patent validity by a quasi-judicial organization, for example, as being similar to the ITC of the United States.

(iii) **Limits of judicial relief against patent-infringing goods**

i) The Japanese legal principle does not recognize extraterritorial application of law, according to the Supreme Court judgment in the card reader case. Therefore, in the dispute between Fujitsu Limited and Samsung SDI Co., Ltd. concerning plasma display panel patents, for instance, it was possible to file suits in the United States not only against Samsung America but also against Samsung SDI in South Korea, but suits could only be filed with Japanese courts against Samsung Japan.

ii) If provisions on extraterritorial application were to be established through legislation, Japanese patent holders would be able to file suits with Japanese courts against overseas manufacturers on allegations of patent infringement, based on the new law that allows

extraterritorial application. However, even if a patent holder were to win in such a suit, in order to suspend the overseas manufacturer's production and export, he/she must take the procedure for recognition and enforcement of the Japanese court's final judgment in the country of the overseas manufacturer. In such a case, there is a strong possibility that the Japanese court's judgment would not be recognized and enforced on the basis that the extraterritorial application principle under the new Japanese law runs counter to the territoriality principle according to such a theory as the one adopted by the Supreme Court in the card reader case.

(iv) **Needs for establishing an ITC-style quasi-judicial organization**

In this manner, it is a serious problem that legislation of relevant provisions in Japanese law would not be enough to grant sufficient relief, because in the case of judicial relief, the judgment is rendered in person. Therefore, it would be necessary to establish an ITC-style quasi-judicial organization that can give orders to Customs in border control, and to have such an organization determine not only the patent infringement status, but also the validity of the patent.

This would provide a fair system for importers, allowing them to dispute patent validity. Furthermore, by using the in rem effect of suspending imported goods, it would be possible to effectively suspend patent-infringing goods at the border.

### **3 Border-enforcement systems and procedures as well as their frameworks in other countries**

Taking into account the discussions of the working group, an investigation was conducted on border enforcement in the United States (ITC, customs recordation), Europe (the United Kingdom, Germany, and France), and South Korea (Korea Trade Commission [KTC], Customs Act), and the current situation in each country was summarized. The overview of the results is shown below.

#### **(1) United States**

The International Trade Commission (ITC) conducts the proceedings in the form of adversary proceedings between the parties, so the parties are not likely to find so much unfairness in patent infringement cases where the determination of the infringement status is particularly difficult. Meanwhile, Customs promptly and strictly executes the ITC's orders. The system lacks

speediness with the proceedings sometimes taking about 15 months, but the framework places emphasis on due process. With regard to goods that infringe trademark rights, trade names, and copyright, which are mainly counterfeits and pirated copies, there is a system for enforcement based on customs recordation. Speediness is secured in this framework.

## **(2) Europe (the United Kingdom, Germany, and France)**

In Europe, there is a suspension based on EU regulations and one based on national law. EU members basically use the EU regulations, and use their national law to regulate areas that are outside the scope of the EU regulations.

In Europe, the roles are clearly divided between Customs that accept applications for import suspension and enforce the rights and courts that determine the infringement status. The system is compliant with the rules on the procedures on provisional measures and procedures on the merits of a case under the TRIPS Agreement.

## **(3) South Korea**

South Korea has a system for suspension by the Korea Trade Commission (KTC) and a system for suspension based on the Customs Act. The KTC has a similar structure as the ITC of the United States. While requests for cooperation can be made in the relationship between the ITC and U.S. Customs, Customs in South Korea are not regarded as execution authorities of the KTC. Similar to the ITC, the KTC lacks speediness but places emphasis on due process. In suspension based on the Customs Act, speediness is secured with regard to suspension of goods that infringe trademark rights and copyright. When there are doubts regarding the infringement status, the right holder can file a suit with the court while taking procedures to hold up customs clearance. This point also is compliant with the rules on the procedures on provisional measures and procedures on the merits of a case under the TRIPS Agreement.

(Senior Researcher : Isao HYUGAJI)

