7 Study on the Desirable Form of Rights in the Pro-Patent Era

It is difficult to comprehend how the compulsory license system in Japan on patent rights or the like shall be applied and utilized, because of respective relevant provisions in laws and regulations such as the Patent Law, implementation guidelines of the compulsory license system, the TRIPS Agreement, and the agreement between Japan and the U.S. Therefore, this study picked up "patents on pharmaceuticals," "technical standards (including various issues under the Antimonopoly Act)" and "correction of unfair competition practice" as major examples, and examined whether the compulsory license system can be effectively applied with respect to them. Furthermore, the structure of the compulsory license system was reviewed by making clear the consistency of the legal system of Japan with treaties and international agreements (the TRIPS Agreement and the agreement between Japan and the U.S.) as well as the requirements for application of the compulsory license system. Apart from whether or not any domestic legislative measures should be required to comply with such related treaties and agreements, this study touched upon how the system should be considered from the viewpoints of industrial promotion measures and foreign policies of Japan.

I Access to Pharmaceuticals and Patents

1 AIDS Drugs and Availability

In 1981, HIV (human immunodeficiency virus: AIDS virus), a virus that causes death by destroying the immune system, was found in the U.S. It is thought that during the twenty years since then, 60 million people have been infected with AIDS, and 22 million of them have died. As of December 2000, 36 million people were infected, including 25 million in sub-Saharan countries, accounting for 70% of those worldwide.

AIDS drugs are very expensive and annual expenses for treatment (including the cost of medicine) per patient in the U.S. amount to ten thousand U.S. dollars, and hence it is impossible to pay for treatment required for the people of sub-Saharan countries in which per capita annual domestic income is only 340 U.S. dollars. Under the circumstances, developing countries have reached the consensus that "AIDS drugs are expensive because they are protected by patents. To solve this problem, measures need to be taken such as granting compulsory license or the like."

2 Present Situation in Developing Countries and Patents on Pharmaceuticals

(1) Brazil

Since Brazil has positively coped with AIDS by taking such measures as providing AIDS patients and carriers with AIDS drugs free of charge, the number of dead and the ratio of infection is very small. However, since the enormous expenses for purchasing medicines tightened financial conditions, the Brazilian government had directly negotiated with AIDS drugs manufacturing companies in industrialized countries to press them for reduction of prices against a background of imposition of the compulsory license. At the end of August 2001, F. Hoffman-La Roche Ltd. agreed to reduce the supply price of the company's drug "nelfinavir" by 40%, and as a result, the Brazilian government withdrew once announced enforcement of the compulsory license (this resulted in a decrease in the cost borne by the government from 885 thousand U.S. dollars to 354 thousand U.S. dollars). Brazil had been consistent in its policy not to grant patents on pharmaceuticals, but revised the Patent Law to comply with the TRIPS Agreement at the same time when the World Trade Organization (WTO) was established, and moreover in 1996 adopted the pipeline protection system (a system of retroactively granting patent rights to patent applications for medicines under the old law) under the TRIPS Agreement-Plus. As a result, the introduction of foreign capital from international pharmaceutical businesses and their direct investments have been promoted and employment was increased.

(2) South Africa

In South Africa (hereafter referred to as "SA"), AIDS is widespread, with a high rate of mortality. The country's per capita national income is only 3,160 U.S. dollars, and therefore, it is impossible to pay for the treatment of AIDS. Hence, the government of SA amended the Medicines Act in 1997 to legalize the domestic production of generic pharmaceuticals and parallel importing, and as a result, the Pharmaceutical Manufacturers Association of South Africa and 39 pharmaceuticals businesses in industrialized countries filed a lawsuit against the government of SA alleging that the amended Act was unconstitutional, and the governments of the industrialized countries supported the lawsuit. In April 2001, the lawsuit was withdrawn, whereupon

the government of SA announced a view that the plaintiff and the governments concerned had understood the compliance of the amended Medicines Act with the TRIPS Agreement. On the other hand, however, the plaintiff and the governments of the industrialized countries denied that they had such an understanding.

At present, negotiations on gratuitous grants and a reduction in price are under way between the government of SA and pharmaceuticals businesses in industrialized countries, and the import and parallel importing of patented medicines are being conducted. Merck & Co., Inc. announced that it would not exercise the patent rights concerning its AIDS drugs for five years for Aspen Pharmacare, the largest pharmaceuticals manufacturer in SA, which claimed public attention as voluntary measures that surpassed compulsory licensing. In addition, GSK (GlaxoSmithKline) voluntarily granted free licenses on the patent rights to three types of AIDS drugs to Aspen Pharmacare. Furthermore, Aspen Pharmacare concluded an agreement with GSK to supply 30% of its sales to NGOs for the education on the prevention and treatment of AIDS in consideration of granting of licenses.

(3) India

The present Patent Law handles manufacturing methods only as the object of patenting for medicines, and besides, the maximum period for such patents is only seven years. This period is even shorter than that for the development of medicines, so short that a patent will have expired when a medicine is supplied to the market. For this reason, there have been few applications and registrations of patents on medicines, and there was only one patent falling under the international patent classification, A61K, in 1999, and there was none in 2000.

3 Compulsory Licensing System in Developing Countries

(1) Brazil

The compulsory licensing system in Brazil is of the TRIPS Agreement-compliant type. Compulsory licensing is stipulated in Section 3, Articles 68 through 74 of the Patent Law, and when the patentee does not engage in local production (Article 68, Paragraph 1-a) and when the patentee imports products (Article 68, Paragraph 4), a third party is granted a compulsory license for parallel importing.

(2) South Africa

The compulsory licensing system in SA is of the Paris Convention-compliant type. Article 56 of the Patent Act makes the local working requirements compulsory (Paragraph b), and a compulsory license is granted when localization is hindered because no licensing based on an agreement has been made (Paragraph d) or when the price of imports is higher than that in other countries (Paragraph e).

(3) India

The compulsory licensing system of India is of the Paris Convention-compliant type. Article 84 and Article 85 of its Patent Law stipulate compulsory licensing, and not only in the case of non-licensing or insufficient licensing, but even when licensing is sufficient, a compulsory license is also granted if the price of the patentee's product is not reasonable (Article 84, Paragraph 1). It should be noted that the country has provisions on the system of license of right (Article 86), and patents on medicines are automatically subject to compulsory licensing on the basis of the system (Article 87, Paragraph 1). There were eight claims made based on this system for compulsory licenses concerning patents on medicines from 1972 to 1980, three of which were granted compulsory licenses (*1).

4 Views on Compulsory Licensing of Governments and Organizations in Various Countries

Views differ depending on one's position as to whether compulsory licensing is effective in terms of access to medicines. Different opinions were expressed in the special meeting of the TRIPS Council held on June 20, 2001. They are given below.

(1) Views of Developing Countries and More Developed Countries

Zimbabwe, representing the African Group, termed compulsory licensing "an indispensable tool for the government to effectively implement its public health policies." Brazil emphasized that compulsory licensing is an essential element in undertaking price negotiations between the Brazilian government and pharmaceutical manufacturers. Thailand proposed a scheme in which a country that does not have manufacturing capacities within the country grants compulsory licenses (import rights) to manufacturers in other countries, thereby making medicines with affordable prices available within its own country. Cuba stated that, under the situation in which countries must depend on expensive imported medicines, compulsory licenses aiming at importing from countries capable of manufacturing them should be granted.

(2) Views of Industrialized Countries

The U.S. spent time interpreting Article 31 of

(*1) See Mika Yamana "Hattentojoukoku niokeru Tokkyo no Kyousei Jisshi Seido (Compulsory Licensing System of Patents in Developing Countries)", Nihon Kogyo Shoyuukenhou Gakkai Nenpou (Annual Report of Japan Society for Industrial Property Rights Laws) No. 24 (Yuhikaku, 2000).

the TRIPS Agreement from beginning to end, such that each country can adopt the flexibility of the Agreement and that it considers that AIDS falls under the category of national state of emergency, and the like, withholding any evaluation of compulsory licensing itself. In addition, the U.S. merely termed compulsory licensing aimed at exporting "problematic." Japan, like the U.S., did not evaluate compulsory licensing itself, but stated that it was ready to positively study justification of measures to realize compulsory licensing in third countries aimed at exporting, without prejudice to Article 31, Subparagraph (f) of the TRIPS Agreement. The European Union (EU) stated that compulsory licensing in a third country for exporting should be studied seriously without prejudice.

(3) Views of the IFPMA (International Federation of Pharmaceutical Manufacturers Association)

IFPMA expressed its view that "access to medicines and patent rights are not directly related, and access is hindered in developing countries by institutional problems in those countries such as poverty, failure to improve infrastructure, civil war, trade protectionism, and that compulsory licensing could not be the solution to the problem of access to medicines, giving such reasons that: ① price reduction or free grant by the patentee ensures stable supply, rather than compulsory licensing; ② products supplied through compulsory licensing are not guaranteed in quality, safety and efficacy; and ③ of the 306 essential drugs of WHO, only 15 are patented medicines, and the majority of the rest are not related to compulsory licensing, while there is no record showing that access to the latter is easy.

5 Anthrax Terrorism Case and Post-Doha

(1) Anthrax Terrorism Case and Compulsory Licensing

Subsequent to the terrorist attacks in New York on September 11, 2001, anthrax terrorism cases occurred at many locations somewhat simultaneously within the U.S., whereupon the argument was raised in the U.S. Congress and within the U.S. government that Cipro (Ciprofloxacin preparation) of Bayer AG, which is effective as a specific remedy against anthrax, should be subject to compulsory licensing within the U.S. Meanwhile, the FDA (the Food and Drug Administration), the competent authorities of medicines, stated that it was unable to address the matter unless companies other than Bayer AG made applications for the sales of Cipro, thus paying little attention to the enforcement of compulsory licensing.

After the anthrax cases gradually subsided, the issue of compulsory licensing within the U.S. also died down, but it is interesting that in the U.S. amongst strong objections to the enforcement of compulsory licensing, the argument was raised, the compulsory licensing should be enforced upon occurrence of a state of emergency. If the U.S. had enforced compulsory licensing, a precedent would have been set, concerning: ①under what conditions it can be done; ② who the claimant should be; ③ how the conditions of licensing should be determined; ④ the required procedure up to granting licenses; and the like. Another discussion remained unsettled and to be considered in the future is that, in the case where an antimicrobial preparation approved as a medicine against infecting organism other than Bacillus anthracis is found to be also effective against Bacillus anthracis, whether or not the authorities in charge of the pharmaceutical business permit its uses other than that specified (namely, its application against Bacillus anthracis).

(2) Post-Doha

On the last day of the WTO Ministerial Conference, which was held from November 9 through 14, 2001 in Doha, the United Arab Emirates (UAE), the "Ministerial Declaration on the TRIPS Agreement and Public Health" (WT/MIN(01)/DEC/W/2) was announced, and the following reference to the relation between access to medicines and compulsory licensing is important.

① "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. ... we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to ... promote access to medicines for all."

② "Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV ... can represent a national emergency or other circumstances of extreme urgency."

③ "We recognize that Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement."

④ "We also agree that the least-developed country Members will not be obliged ... to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016..."

The above Ministerial Declaration provided a partial solution to the issues regarding interpretation of the TRIPS Agreement that had been disputed between industrialized countries and developing countries until in the middle of the year 2001, and this was a "complete victory" for

developing countries. This Ministerial Declaration was a political announcement made by bearing in mind the state of emergency - the spread of AIDS, and is not directly binding on WTO member countries, but it seems undeniable that developing countries will quote this announcement to press industrialized countries to implement the announcement into practice.

6 Expected Mode of the Enforcement of Compulsory Licensing and Interpretation of the TRIPS Agreement

(1) Mode of the Enforcement of Compulsory Licensing

As long as complying with the provisions of each subparagraph of Article 31 of the TRIPS Agreement, each WTO member country can establish the right of compulsory licensing, irrespective of the reasons therefor. In accordance with the above ④ of the Ministerial Declaration, the compulsory licensing system based on each country's respective legal system will be applied until January 1, 2016, and until then, the purposes of access to medicines are roughly divided into: ① domestic manufacturing; and ② import from overseas without domestic manufacturing (including the case where no manufacturing capacity is available).

① Compulsory licensing for local manufacturing

The reasons for granting compulsory licensing for local manufacturing include: (a) the patentee does not work the patented invention or works it insufficiently; (b) the patentee only imports the products; (c) the price of the products made by the patentee is high; (d) the patentee engages in local manufacturing or importing, but there is need to grant compulsory licensing unconditionally for public welfare (old Canadian Patent Law); and so on. However, (b) violates Article 27 of the TRIPS Agreement, which reads: "patent rights enjoyable without discrimination as to ... whether products are imported or domestically produced," as well as Articles 28 and 30 of the Agreement; the "price is high" in (c) is arbitrary or subjective, being ambiguous as the criteria for judgment, and hence violates Articles 28 and 30 of the Agreement; and (d) is problematic in relation to Article 27 of the Agreement, and the like.

In either case of the above categories, if the patentee does not agree to granting compulsory licensing, then in accordance with Article 31, Subparagraph (i) of the Agreement, a judicial decision shall be sought in a court of law in the country where compulsory licensing has been granted, about the effectiveness of compulsory licensing. If there is any objection to the system of the granting country, the matter shall be settled in the dispute settlement panel of WTO after negotiations between the two countries concerned. The final settlement can only be made by the panel.

② Compulsory licensing for import

"Import" includes parallel importing. The TRIPS Agreement does not consider parallel importing (Article 6) and it is solely a matter of interpretation of domestic law, and therefore such domestic legislative measures can be taken as to make parallel importing lawful, or grant compulsory licensing for parallel importing, and the like. Moreover, the Doha Declaration recognizes that "The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge ...," and so parallel importing can be a powerful tool for access to medicines.

Usually, in the case of import from a third country (Country B), whether or not the patent right exists in Country B is concerned. If there is no corresponding patent right in Country B, then it is solely a problem of the country that intends to enforce compulsory licensing (Country A) for obtaining medicines, but if there is a corresponding patent right in Country B, then the problem of infringement of patent right arises in the country. Therefore, Country B may grant compulsory licensing to a business that manufactures patented medicines with a view to exporting them to Country A, but in this case "predominantly" in Article 31, Subparagraph (f) of the Agreement is problematic. Compulsory licensing is a right granted within the range of a patent right, and it should not be established with a view to eliminate inconvenience in other countries. Such a technique is out of the question in which compulsory licensing is enforced in Country B, and nominal "domestic" sales are carried out in Country B to avoid the "predominantly," thereby exporting most of the products (to Country A). In the Doha Declaration, this problem was sought to be solved mainly by interpretation, however, it should be solved by revision of the TRIPS Agreement.

(2) Problems to be Solved

Problems regarding access to medicines involve multiple factors and are difficult to be solved. An attempt to easily solve these by granting compulsory licensing may result in a decrease in the level of protection of patent rights, which may even hinder R&D investment into AIDS drugs. The very fact that such withdrawal from the investment is occurring should be considered more worrisome. This problem is not only reflected in the number of registrations in India, it has frequently occurred in Canada, which is one of the G7 industrialized nations, after compulsory licensing had been institutionalized until about ten years ago.

Ⅱ Technical Standards and the System of Compulsory License

1 Problems in Technical Standardization

Standardization of technical specifications and standards is important in products and services such as telecommunications equipment, computer software, etc. where utility arises when they are connected with other users and other equipment. IC cards, DVDs, next-generation TVs, mobile phones, PC communication, etc. would be the most typical examples. Technical standards can roughly be divided into the followings, according to the process of their standardization.

① Public standards devised by public standardization organizations;

② Where technical specifications and standards of specific businesses become the technical standards as a result of market competition;

③ Technical standards devised by trade associations or through agreement among multiple businesses.

① is called "de jure standard" and is devised by public organizations such as ISO (International Organization for Standardization), IEC (International Electrotechnical Commission), and the like. ② is called "de facto standard." In addition, recent activities aiming at technical standardization, not through public standardization organizations, or originating from such a sphere, with multiple businesses gathering together have been taken place. This falls into the category of ③ above, and is called a forum or consortium (hereafter collectively referred to as a "Forum").

2 Patent Policies of Forums and its Limitations

The patent policies of Forums are not uniform. They can be divided into those having no patent policy at all, those complying with the rules of ISO, etc., or those having an original patent policy, or the like. Forums having patent policies are concerned about patentees' powerful exertion of absolute exclusive rights, and in order to propagate the standards widely, make enormous efforts to limit licensing fees paid by users within a reasonable range, and at the same time to satisfy the profits of the right-holders within a certain range, thereby making a system to increase the number of participants of the holders of essential patents as much as possible.

However, whatever patent policies are provided for by various technical standardization organizations including Forums, patent problems have not been settled completely. For example, if a patentee of an essential patent for certain technical standards leaves a Forum, or the patentee has not participate in the Forum without intention to do so from the beginning, then a license needs to be obtained from such a patentee separately, and hence the function of the Forum will not be fully realized. Moreover, there have been unreasonable situations where the license fees received by a patentee who does not participate in a patent pool organization and has concluded licensing contracts on his/her own are higher than the license fees received by a patentee who does participate in a patent pool organization.

3 Possibility of Right of a Non-exclusive License Granted by an Arbitration Decision (*Saitei Jisshiken*)

It is also possible that a holder of an essential patent proposes unreasonably high license fees to a company, and the company can obtain no licensing practically, or the license is rejected, thus being unable to continue its business (Hold Out). If this occurs at the stage of devising specifications of standard technologies, there is room for selecting technical standards that do not use the invention related to such the patent, but if this occurs after the adoption of standards, the propagation of the technical standards will be hindered. Some people in the industrial sector who are concerned about the possible occurrence of such a situation, strongly support the effectiveness of the compulsory license system(*2).

MPEG2 standards will be studied hereafter as a concrete example. As a precondition, it is assumed that Patentee, i.e., Company A that holds a patented invention essential for MPEG2 standards and that does not participate in a patent pool, has asserted its rights based on the patent rights against Company B, a manufacturer of MPEG2 standards products (for example, a manufacturer of TVs or DVD equipment) that pays license fees to a MPEG2 patent pool.

(i) Article 93 of the Patent Law

If Company B makes a request for an arbitration decision (*Saitei*) based on Article 93 of the Patent Law, it must specify the requirement of "Working of a patented invention is particularly necessary in the public interest." In brief, it is a matter as to whether the manufacture and sale of products complying with MPEG2 standards by Company B are particularly necessary in the public interest. Even when the MPEG2 standards themselves are deemed to have public nature, there is no public nature in "Company B's" actions themselves for the manufacture and sale of the products. If Company A asserts its rights against all

(*2) See Takashi Sawai "Melbourne Kokusai Soukai no Gidai ni taisuru Nihon Bukai no Iken (Opinions of Japan Sectional Meeting to the Agenda of World Congress in Melbourne) (3)", A.I.P.P.I. Vol. 45, No. 11, p. 25 et seq. (2000).

the manufacturers of MPEG2 standards-compliant products, and it is expected that the assertion will be admitted, whereby ordinary consumers will not be able to obtain the products, to be deprived of the opportunity to use high-quality moving pictures, then the working of the patented invention that Company A possesses by all the manufacturers inclusive of Company B, can be evaluated as being "particularly necessary in the public interest."

It should be noted here that the right of a non-exclusive license granted by an arbitration decision under this article should not be applied to all the problems of Hold Out that can occur with reference to technical standards in all the standards and fields. That is to say, only when substantial Hold Out occurs to the technical standards that have already become a social infrastructure, or that is expected to become a social infrastructure in the future to a considerable extent, a right of a non-exclusive license by an arbitration decision should be granted to a patent concerning the technical standards.

(ii) Article 83 of the Patent Law

"Where a patented invention has not been sufficiently and continuously worked during a period of three years or more in Japan" (and where four years have elapsed since the filing date of the application corresponding to the patented invention), a request for a non-exclusive license by an arbitration decision under this article may be made, and so if Company A has not worked the patented invention at all, and has not granted a license to any other company, then there is room for applying this article.

If Company A works the patented invention in the manufacture and sale of MPEG2 standards-compliant products, then it is a precondition for Company A to receive a license of a patent of the MPEG2 patent pool. And then, in order for Company A to become a licensee of a patent of the MPEG2 patent pool, Company A must grant a license of its patent essential for MPEG2 (grant back) to all the licensees of the MPEG2 patent pool (as stipulated in the MPEG2 License Policy), and therefore such a situation cannot occur that Company A asserts its rights against Company B in connection with the essential patent.

(iii) Article 92 of the Patent Law

If Company B does not possess any patented invention that has a relation of dependency with the invention related to the essential patent possessed by Company A("dependency" means that the former invention shall utilizes the latter invention), then the provisions of this article shall not be applied. In addition, even if Company B possesses a patented invention that has such a relation of dependency, the provisions of this article shall not be applied unless the dependent invention involves "an important technical advance of considerable economic significance" of Article 31, Subparagraph 1 of the TRIPS Agreement.

Ⅲ Problems with Antimonopoly Act regarding Technical Standards

1 Relation between the Intellectual Property and Antimonopoly Act

Article 21 of the Antimonopoly Act stipulates that "the provisions of this Act (= Antimonopoly Act) shall not apply to such acts recognizable as the exercise of rights under the Copyright Act, the Patent Act, the Utility Model Act, the Design Act or the Trademark Act." It is commonly held that this is a corroboration rule, of which application to such actions as should be originally held to be illegal is not to be excluded. Regarding this, there was a dispute over what is the due exercise of patent rights and the like, while the Fair Trade Commission (Kosei Torihiki Iinkai) expressed an official opinion in the "Tokkyo Kow-how License Keiyaku ni kansuru Dokusen Kinshi Hou jou no Shishin (Guidelines for Patent and Know-how Licensing Agreements under the Antimonopoly Act)," as was announced publicly on July 30, 1999. In the policy, if the actions are not deemed to be the "acts recognizable as the exercise of rights," then the Antimonopoly Act shall be applied thereto. It mentions as the examples that are not evaluated as being the "acts recognizable as the exercise of rights," (1) the case in which the actions are deemed to, on the pretext of the exercise of rights, be carried out as actions that form part of the unreasonable restraint of trade or private monopolization that violates the Antimonopoly Act, or be carried out as the means of these, or the like; and (2) where they are deemed to be against the aim or purpose of the system to protect technologies when being seen from the purpose or mode of the actions, or from the gravity of the influence of the actions in question on the order of competition in the market.

2 Problems with the Competition Policy

As the problems on the Antimonopoly Act or the competition policy regarding technical standards, the following three examples are given below.

(1) Rejection of Participation in the Work of Devising Technical Standards

Unlike de facto standard that arises out of competition, the technical standards resulting from a Forum have the danger of being devised and maintained in an anti-competitive way. The viewpoint under the Antimonopoly Act on this problem is explained in the "Kyoudou Kenkyu Kaihatsu ni kansuru Dokusen Kinshi Hou jou no Sishin (Guidelines under the Antimonopoly Act

Concerning the Joint Research and Development)," as was announced publicly in April 1993 by the Fair Trade Commission. According to the Guidelines, whether or not to make a person participate in the joint research and development is left to his/her free will as a general rule. In the joint research and development that aim at devising standards, the participation of specific entrepreneurs are restricted, whereby the business activities are difficult to be carried out, and may be excluded from the market, then it may violate the Antimonopoly Act as an exceptional case. However, if the businesses of which participation has been rejected are assured of their access to the results of research and development, and if there is no danger that their business activities will be made difficult, then it will not become problematic.

(2) Rejection of Licenses of Technical Standards

The Antimonopoly Act clearly distinguishes the rejection of transactions by joint actions (joint boycott) from the rejection by a single business, with reference to the illegality of the rejection of transactions inclusive of the supply of licenses. The rejection of transactions is highly illegal if it is carried out by joint actions of multiple businesses (inclusive of actions by an association of businesses), and if it restricts competition substantially, then it constitutes the "unreasonable restraint of trade," and even when the degree of restraint of competition is low, it becomes illegal as an "unfair trade practices" (General Provision, Section 1) as a general rule. Therefore, whether or not there is cooperativeness becomes important, while the following explanations on the problems of license rejection with respect to techniques employed in the standards are given in the "Gijutsu Hyoujun to Kyousou Seisaku ni kansuru Kenkyu Houkokusho (Report of the Meeting for the Study of Technical Standards and Competition Policies)" of the Fair Trade Commission as was announced publicly on July 25, 2001:

(i) The rejection of licenses by a right holder within a Forum violates the Antimonopoly Act

Such a rejection of licenses falls under the category of a joint rejection of transactions, and is not evaluated as being the exercise of rights under the Patent Law, etc. Therefore if the business activities of the rejected business become difficult, whereby competition is substantially restricted, then it constitutes the "unreasonable restraint of trade" or "private monopolization." The same applies to the case of a rejection of licenses by one right holder within a Forum, if it disables the use of technical standards, whereby the business activities of the rejected business become difficult to be carried out.

(ii) In the case of a rejection of licenses by a right holder outside of a Forum, its evaluation under the Antimonopoly Act varies depending on whether or not there is involvement in the work of devising the standards. If the holder is unaware of the incorporation of his/her technologies into the standards, or the holder expressed clearly his/her intentions to be opposed thereto, it does not become a problem under the Antimonopoly Act as a general rule. Conversely, if the holder has made efforts to make his/her own technologies incorporated into the standards, or after the technologies of his/her own company have been incorporated into the standards, he/she has acknowledged tacitly that they are incorporated into the standards by taking such an action as granting a license thereof to other companies, or the like, or otherwise if the holder has withdrawn from a Forum after he/she once was involved in the work for standardization within the Forum, then it may be a problem under the Antimonopoly Act.

Therefore, the rejection of licenses by a right holder (a business or entrepreneur) with reference to the patent rights, etc. possessed by itself is the "exercise of rights" as a general rule, and does not violate the Antimonopoly Act. Such a rejection of licenses constitutes the violation of the Antimonopoly Act in such exceptional cases as: ① being made by an entrepreneur that is market-dominant; ② any anti-competitive intentions or aims have been added; ③ preventing the creation of new technologies or the development of new products.

With reference to the above, the problem of expensive license fees is also mentioned below. The Antimonopoly Act is not to regulate the level of the amount of license fees itself. However, if it is so expensive as to be regarded as being equal to the rejection of licenses, then it is dealt with as a problem of a rejection of transactions. In addition, such an act as not asserting the rights at first, but demanding expensive license fees after standardization, may be a problem under the Antimonopoly Act. Moreover, the demand of expensive license fees may fall under the category of the "abuse of a dominant status" (General Provision, Section 10) when being seen from the process in which certain technologies have become the technical standards. However, the provisions of the abuse of a dominant status are abstract provisions, which should not be frequently abused. In this regard, the EU Competition Act has the provisions of an abuse of a market-dominant status (Article 82 of the Treaty of Rome), which enables the setting of high prices by a dominant entrepreneur itself to be illegal.

(3) Problems of an Unfair Competition Means to Acquire Technical Standards

There is a danger that an unfair competition means is used to acquire technical standards. If the number of persons (businesses) that wish to work patented inventions possessed by a business increases, then the inventions (technologies) become the technical standards at an early stage,

and the business can obtain a dominant status in the market, and also can expect to obtain the income resulting from license fees. Included in the actions that become problems under the Antimonopoly Act are: deceptive activities of propaganda; transactions of tie-in sales; transactions with exclusive conditions; sales at unjustly low prices; and the like.

3 Elimination Measures against Actions in Violation of the Antimonopoly Act

Granting compulsory licenses as the measures to correct anti-competitive practices is allowed internationally as well (Article 31 (k) of the TRIPS Agreement and the agreement between Japan and the U.S.). Meanwhile in Japan, measures to correct violation practices (hereafter referred to as the "elimination measures") are stipulated in Article 7, Article 8-2 and Article 20 of the Antimonopoly Act. Based on these elimination measures, the Fair Trade Commission may order that the action to be ceased, a part of the business be transferred, the association of entrepreneurs be dissolved, the clauses concerned be deleted from the contract and any other "measures necessary to eliminate ... acts in violation." Hence, if intellectual property rights are involved, it can be interpreted that, as these concrete necessary measures, the compulsion of the licenses of patent rights and the like can also be ordered.

Included in the examples in which measures related to intellectual property rights were ordered in the cases of the violation of the Antimonopoly Act, are: (a) an example in which the supply of manufacturing technologies in consideration of reasonable license fees was ordered (the case of the merger of Yawata and Fuji: Trial Decision of Consent on October 30, 1969, 1969 (Han) No. 2, Shinketsushu (Collection of Trial Decisions), Vol. 6, p. 46); (b) an example in which it was ordered to accept even a proposal for licenses covering a part of the software only (the case of Microsoft Japan: Trial Decision of Recommendation on December 14, 1998, 1998 (Kan) No. 21); (c) an example in which a withdrawal of an application for trademark rights was ordered (the case of The Hokkaido Shimbun Company, Trial Decision of Consent on February 28, 2000, (Han) No. 2, Shinketsushu (Collection of Trial Decisions), Vol. 46, p. 144, Tokuho (Special Report) No. 1964). In addition, (d) the case of pachinko machine patent pool (Trial Decision of Recommendation on August 6, 1997, 1997 (Kan) No. 5, Shinketsushu (Collection of Trial Decisions), Vol. 44, p. 238) is a case of private monopolization by a patent pool management company, and while the trial decision of this case was merely to make the policy to prevent new participation withdraw, a scholar criticized it by stating that competition cannot be recovered unless the new participant receives licenses, and so compulsory licensing with reasonable royalties should have been ordered(*3).

In the U.S., there is an example in which The Federal Trade Commission ordered a monopoly entrepreneur to grant compulsory licensing of patent rights and to supply technical information of reasonable royalties(*4). In addition, in a case where a merger becomes a problem under the Antimonopoly Act, as measures to resolve the illegal state, compulsory licensing may be ordered, which is thought to be more acceptable for businesses than the division of a business. In the U.S., there is an example in which, as the conditions to permit the merger of Ciba-Geigy Ltd. and Sandoz Ltd., granting licenses of the patents that overlap between the two companies (patents in the anticancer drugs market as an innovation market) to other companies was ordered.

4 Relation between the System of Compulsory License and the Antimonopoly Act

As a method by which the government orders that an entrepreneur rejecting granting licenses should be subjected to compulsory licensing, besides the measures based on the Antimonopoly Act, the system of compulsory license based on the Patent Law is employed. Even when not being in violation of the Antimonopoly Act, from the viewpoint of the policy of intellectual property laws, to give some examples: if the public interests are damaged because of the excessive protection of technical standards by intellectual property rights, then the right of a non-exclusive license granted by an arbitration decision as set forth in Article 93 of the Patent Law shall be established; and if too broad exclusive rights are given to the patented inventions of prior technologies, then there is a danger that the working of improved patents that "involve an important technical advance of considerable economic significance" (Article 31 (l) of the TRIPS Agreement) will be hindered, and hence the right of a non-exclusive license granted by an arbitration decision as set forth in Article 92 of the Law shall be established. In short, it is a matter of comparison and consideration of relative advantages between the protection of intellectual

(*3) Negishi et al., "Zadankai Saikin no Dokusen Kinshi Hou Ihan wo megutte (Round-table talk: Over the recent cases violating the Antimonopoly Act)", Kousei Torihiki (Fair Trade) No. 572 (1998), Masahiro Murakami "Pachinko Ki Patent Pool Jiken Kankoku Shinketsu wo megutte (Ge)(Over the Trial Decision of Recommendation on the Case of Pachinko Machine Patent Pool (II))", Kousei Torihiki (Fair Trade) No. 570, p. 59 (1998).

(*4) See American Cyanamid Co. v. FTC, 363F, 2d 126 (6th Cir, 1971).

property rights and the protection of the public interests by promoting competition. By considering that the elimination of anti-competitive actions and the promotion of competition are the "public interests," these are the same as the criteria of illegality standard of the Antimonopoly Act. Namely, an entrepreneur to which granting licenses was rejected takes judicial or administrative procedures prior to the request for an arbitration decision, and is given the certification of the violation of the Antimonopoly Act, to be then granted the right of a non-exclusive license by the Commissioner of the Patent Office or the Minister of Economy, Trade and Industry. (Article 92, Article 93 of the Patent Law, Article 31 (k), (l) of the TRIPS Agreement, Item ③ of the agreement between Japan and the U.S., the foregoing to be described later.)

Ⅳ System of Compulsory License and the TRIPS Agreement

1 Necessity to Secure Consistency with the TRIPS Agreement

Each WTO Member country shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements to the Marrakesh Agreement Establishing the World Trade Organization (Agreement Establishing the WTO) (Article 16, Paragraph 4 of the Agreement Establishing the WTO). The system and measures in violation of the TRIPS Agreement (Annex 1C) may be subject to the procedure of the settlement of disputes by the Dispute Settlement Body (DSB) in accordance with Article 64, Paragraph 1 of the TRIPS Agreement (Article 23 of GATT as applied therein) and the Dispute Settlement Understanding (DSU). In cases where there is a violation of the agreement, it is presumed that there exists nullification or impairment unless there is rebutting evidence (Article 3, Paragraph 8 of DSU), and the recommendations of DSB that call for the consistency with the agreement are finally backed by sanctions that cover all the fields of WTO, which are called the cross-retaliation. Thus WTO has had strong mechanisms to have its Member countries fulfill their obligations.

Under the circumstances, it should be ensured that the system in Japan is consistent with various agreements of WTO.

(1) Relation between Article 26 of the Patent Law and the Treaty

Article 26 of the Patent Law stipulates that "where there are specific provisions relating to patents in a treaty, such provisions shall prevail." In accordance with provisions of the Constitution of Japan, it is construed that a treaty has domestic effects and has priority over the laws, and it should be construed that Article 26 of the Patent Law only stipulates this in a corroborative and attentive way(*5). However, the article is not to stipulate that there is a possibility that the treaties related to patents have direct domestic adaptability. Namely, the article is construed that not all the provisions of a treaty are directly applied to the people, but those which a nation is obligated or allowed to domesticate by judging from the words and characters contained therein, can only be utilized after they have been incorporated into domestic laws(*6).

(2) Direct Domestic Adaptability of the TRIPS Agreement

(i) U.S.

The U.S. has completely denied the direct domestic adaptability of WTO agreements. Namely, the Uruguay Round Agreements Act stipulates that ① No provision of any of the WTO agreements that is inconsistent with any law of the United States shall have effect (Section 102 (a)(1)); ② Nothing in this Act shall be construed to amend or modify any law of the United States ((a)(2) of the Section); ③ No State law may be declared invalid on the ground that the provision or application is inconsistent with any of the WTO agreements, except in an action brought by the United States for the purpose of declaring such law or application invalid ((b)(2)(A) of the Section); ④ No private individual shall make, in process of litigation, any assertion based on any of the WTO agreements, or may challenge any measures taken by the United States, any State, or any political subdivision of a State on the ground that they are inconsistent with the various WTO agreements ((c)(1) of the Section).

(ii) EC (European Community)

In the preamble of an EC Council Decision in 1994 that approved the acceptance of the Agreement Establishing the WTO, it is clearly stated that the Agreement is not directly applied in EC. In addition, the EC court (European Court of Justice) ruled in 1972 that an individual cannot seek the protection of his/her rights in a court based on Article 11 of GATT, and denied the direct domestic adaptability of GATT in relation to the EC law (International Fruit Company judgment - cases 21-24/72). In 1983 the direct domestic adaptability of GATT was denied in relation to the domestic laws of EC member countries as well (SIOT judgment - case 266/81). After the establishment of WTO, because of the "judicialization" of the

(*5) Yuji Iwasawa "Jouyaku no Kokunai Tekiyou Kanousei (Domestic Adaptability of Treaties)", p. 331 (Yuhikaku, 1985), Written and edited by Nobuhiro Nakayama "Chukai Tokkyo Hou Joukan (Annotations - Patent Law I)", p. 204 (Nobuhiro Nakayama)(Seirin Shoin, Third Edition, 2000).

(*6) Nakayama, ibid., Note 5, p. 204.

procedure of the settlement of disputes, its outcome became the focus of attention, and in the Hermès judgment in 1998 (case C-53/96) the direct domestic adaptability of Article 50 of the TRIPS Agreement became an issue, but the court did not show the decision on this issue(*7).

The most serious problem in affirming the direct domestic adaptability of the WTO agreements is that both of the member countries that are important partners of negotiations (U.S. and EC) deny the direct domestic adaptability of the agreements. That is to say, if only Japan affirms the direct domestic adaptability of the agreements, it may make Japan hold less bargaining power, resulting in damage to national interests. This is because, countries in which the existing domestic laws are given priority at all times even after the agreements have been concluded (U.S. and EC) are unlikely to enter into negotiations, during the process of concluding the agreements, in an equal bargaining position with countries of which domestic laws that contravene the agreements lose effects immediately after the agreements are ratified. The reason that a judicial official ruled in the case of Hermès that there is a serious obstruction in acknowledging the direct effect of the TRIPS Agreement in EC court also arises from such mutuality among member countries.

2 "Operational Instructions of the System of Compulsory License)" of the Patent Law (*8) and the TRIPS Agreement

(1) Article 31 of the TRIPS Agreement

Article 31 of the TRIPS Agreement stipulates the conditions and the like in the case where a member country permits the use of a patent without the authorization of the right holder, including granting compulsory licenses or use by the government, etc.(*9) Matters that form the points at issue with respect to the consistency of the Article with the Patent Law are outlined below.

(i) Subparagraph (b) (the case of a national emergency or the like)

Article 31, Subparagraph (b) waives the obligations to enter into negotiations in the case of a national emergency or in cases of public non-commercial use. Meanwhile, in the system of compulsory license in the Patent Law, provisions in the case of a national emergency are not set forth, and in cases of public non-commercial use as well, it is required to follow the same procedures as those in the other cases. Therefore, since Japan's system of compulsory license provides substantial protection more than the agreement for the patentee, there occurs no problem under the Agreement, which employs the minimum standard principle (Article 1, Paragraph 1 of the Agreement).

(ii) Subparagraph (c) (the reason for granting patents for semiconductors)

Subparagraph (c) permits granting compulsory licenses for patents related to semiconductor technology only in the cases: ① of public non-commercial use; and ② to remedy an anti-competitive practice. Japan's Patent Law provides for rights to request for an arbitration decision by reason of non-working (Article 83 of the Law), relation of dependency (Article 92 of the Law) and public interest (Article 93 of the Law) and the requirement for the enforcement of each of such rights. However, the TRIPS Agreement does not permit compulsory license at all concerning patents related to semiconductor technology on the ground of Article 83 and Article 92 of the Patent Law, and the compulsory license by reason of Article 93 of the Law is not permitted except in the cases of ① and ② above. Since the Operational Instructions set forth that an arbitration decision shall be made in compliance with the TRIPS Agreement, the Commissioner of the Patent Office or the Minister of Economy, Trade and Industry are not likely to issue an arbitration decision that contravenes Subparagraph (c).

The problem lies in such a case that, concerning patents related to semiconductors, a request for an arbitration decision is made based on the provisions of Article 93 of the Law except ① and ② above, and the Commissioner of the Patent Office or the Minister of Economy, Trade and Industry takes a measure to reject this request by reason of Subparagraph (c), and thereafter the measure is disputed in administrative litigation. If the direct domestic adaptability of Subparagraph (c) is affirmed, then Article 83, Article 92 and Article 93 of the Patent Law are not in effect as long as they contravene Subparagraph (c), and so there arises no problem of illegality when a measure is taken to reject the request . On the other hand, when being based on an opinion that denies the direct domestic adaptability of Subparagraph (c), concerning patents related to semiconductors as well, the provisions of the Patent Law that enable

(*7) For details, refer to Iwasawa, ibid., Note 5, pp. 258 - 263, Yuji Iwasawa "WTO no Funsou Shori (WTO's Settlement of Disputes)" pp. 60 - 67 (Sanseido, 1995), Yuko Yamane "Kokusai Hou to EC Hou Chitsujo (Ge) Chokusetsu Kouka no Jouken (International Law and the Order of EC Law (II), Conditions of Direct Effects)", Toki No Horei, No. 1585, p. 65 (Printing Bureau of the Ministry of Finance, 1999).

(*8) Industrial Property Council, Ministry of International Trade and Industry "Saitei no Unyou Youryou (Operational Instructions of the System of Compulsory License)" (1975).

(*9) For detailed explanations of the contents of provisions of each subparagraph of Article 31 of the TRIPS Agreement, see Akira Ojima "Chikujou Kaisetsu TRIPS Kyoutei (Explanations Article by Article of the TRIPS Agreement" (Nihon Kikai Yushutsu Kumiai Japan Machinery Center for Trade and Investment, 1999).

the right of a non-exclusive license granted by an arbitration decision according to Article 83, Article 92 and Article 93 of the Law are still in effect, and Subparagraph (c) does not become a standard for trial in a domestic court of law. Therefore, concerning the request for an arbitration decision based on the Patent Law, the measure to reject the request based on Subparagraph (c) without conducting any substantive examination is illegal. From the foregoing, it would be required that, under the present situation in which a decisive judgment is difficult to be made about the direct domestic adaptability of Subparagraph (c), requirements of the above ① and ② should be clearly stated in the law as limitative reasons that enable an arbitration decision to be enforced concerning patents related to semiconductors.

(iii) Subparagraph (k) (permission for the purpose of remedying anti-competitive practices)

Subparagraph (k) provides for conditions of permission in the case of aiming at the remedy against anti-competitive practices. Such a purpose falls under the category of "public interest" set forth in Article 93 of the Patent Law, and so that the Article is consistent with the TRIPS Agreement. Note that whether or not provisions on an arbitration decision with a view to remedying anti-competitive practices should be added to the Patent Law is a matter of Japan's policies on industry and competition, and the contravention with the Agreement does not cause any problem.

(iv) Subparagraph (1) (dependent invention)

Regarding the permission with reference to the dependent invention as set forth in Subparagraph (1)(i), it is required that the second patent shall "involve an important technical advance of considerable economic significance," but this requirement is not provided for in Article 92 of the Patent Law. Paragraph 5 of the Article stipulates that, if the grant "would unduly injure" the interests of the patentee or the like, then an arbitration decision shall not be rendered, and the Operational Instructions state that in such a case, "the contents of the patented invention of prior application and the like as well as patented invention of later application" shall be taken into account. Where, if the Commissioner of the Patent Office undertakes an operation in accordance with Subparagraph (1)(i) that no arbitration decision shall be rendered if the above requirements are not satisfied, then there arises no problem under the Agreement. Even if the direct domestic adaptability in Subparagraph (l)(i) has been denied, it is evident that, determining the arbitration decision in consideration of the above requirements is within the range of discretion of the Commissioner of the Patent Office, and there arises no problem of illegality. Note that aside form this Subparagraph, there also is the consistency of the agreement between Japan and the U.S. with the Patent Law to be considered, which will be described in the next chapter.

(2) Article 27 of the TRIPS Agreement

There is a provision to prohibit comprehensive discrimination in the second sentence of Article 27, Paragraph 1 of the TRIPS Agreement. This article is a provision intended mainly to prohibit "granting compulsory licenses for the reason that, where the patented object is only imported and not produced domestically, the patent is regarded as not being worked."

While Article 83 of the Patent Law is the provisions on the arbitration decision in the case of non-working patents, Article 2, Paragraph 3, Subparagraph 1 of the Law clearly defines that "importing" is one of the modes of "working." Meanwhile, the Operational Instructions explain that, the "case in which only importation is made and production is not carried out domestically" by the patentee falls under the category of the case "where a patented invention has not been sufficiently and continuously worked" in Article 83, Paragraph 1 of the Law, but no such interpretation holds true. Therefore, the Patent Law itself is consistent with Article 27, Paragraph 1 of the TRIPS Agreement, but the aforementioned part of the Operational Instructions is not consistent with the definition in the Patent Law and Article 27, Paragraph 1 of the TRIPS Agreement, and besides, it also contradicts Japan's stance of negotiations in the negotiations of TRIPS. Therefore it is considered appropriate that the part of the Operational Instructions be deleted.

3 Compulsory License on Patents Related to Technical Standards, the Health of the People, and the Like

(1) Standpoint of the TRIPS Agreement

Article 31 of the TRIPS Agreement does not prove any limitation to the reason of granting compulsory licenses and the like, except in Subparagraph (c) related to semiconductor technology and in Subparagraph (1) related to dependent inventions. In the negotiations of TRIPS, from the beginning, industrialized nations including Japan entered into negotiations with a view to prohibiting granting compulsory licenses by reason of "public interests" (granting compulsory licenses for medicines was particularly held to be a problem). Since it became difficult to be implemented, the approach to limit the reasons of grant shifted to the approach to make conditions stricter. Hence, no discussions were made concerning granting compulsory licenses related to the patents on technical standards and the like.

(2) Relation to the Dependent Invention

(i) In the case of patents related to technical standards

If a person who intends to exploit some

technical standards is a mere licensee who does not have the second patent contained in the technical standards, the person cannot make a request for an arbitration decision set forth in Article 92 of the Patent Law. Therefore, if a situation occurs in which a compulsory license is required, it will have to be based on Article 93 of the Law. In this case, however, there arises a problem of an interpretation of the domestic laws as to whether it falls under the category of the case in which to obtain licenses on the patents possessed by the patentee "is particularly necessary in the public interest." Likewise, even in the case in which the licensee who possesses the second patent makes a request for an arbitration decision for reasons of public interests stated in Article 93 of the Patent Law, if its substantial reason is that the standards cannot be worked because the permission of the patentee of the first patent is unable to be obtained, then there also arises a problem that the requirements in Article 31, Subparagraph (1) of the TRIPS Agreement may also have to be satisfied. Regarding the authorization (the Subparagraph) "to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent")," Subparagraph (1) is applied at all times, and so if an arbitration decision is requested to obtain the licenses on the first patent in order to work technical standards, then even an arbitration decision set forth in Article 93 of the Law is naturally required to satisfy the requirements in Subparagraph (1).

(ii) In the case of patents related to the health of the people, and the like

In the case of an arbitration decision set forth in Article 93 of the Patent Law related to the health of the people, and the like, there also are two kinds of problems that are exactly the same as those in the case of the dependent invention stated above.

Ⅴ Evaluation of the Agreement between Japan and the U.S. in August 1994 on the System of Compulsory Licenses on the Dependent Invention

1 Circumstances and Contents of the Agreement between Japan and the U.S.

As the results of the Working Group on Intellectual Property (held three times in total: October, December 1993 and June 1994), which are part of the negotiations of structural problems for each sector in Japan-US comprehensive economic negotiations, "Mutual Understanding on Intellectual Property Rights between the Japanese Patent Office and the U.S. Patent and Trademark Office" (meeting on January 20, 1994) and "Mutual Understanding on Intellectual Property Rights" (exchange of notes on August 16, 1994) were concluded. In the latter (hereafter referred to as the "Japan-US Agreement"), it was confirmed that the Japanese Patent Office will take actions ① to introduce the opposition system after the grant of a patent; ② to revise the accelerated examination system; and ③ to improve the operation of compulsory licenses, and the US Patent and Trademark Office will take actions ① to institute an early publication system; ② to revise reexamination procedures; and ③ to improve the operation of compulsory licenses.

In the Japan-US Agreement, the item ③ regarding measures taken by the Japanese side (hereafter referred to as "Item ③ of the Japan-US Agreement" for short) stipulates that "other than to remedy a practice determined after judicial or administrative process to be anti-competitive or to permit public noncommercial use, after July 1, 1995, the JPO is not to render an arbitration decision ordering a dependent patent compulsory license to be granted"(*10). Therefore, measures were taken to add a revision that "3. Others/ In rendering a compulsory license, the Agreement on Trade-related Aspects of Intellectual Property Rights and other international agreements shall be complied with" to the end of the "Operational Instructions of the System of Compulsory License."

2 Evaluation of the Japan-US Agreement

(1) Legal Nature of the Japan-US Agreement

The Japan-US Agreement is an international agreement between the then Ambassador of Japan to the U.S. and the then Secretary of Commerce realized by exchanging notes. Since it is a treaty in a simplified form made by an exchange of instruments constituting a treaty (Article 13 of the Vienna Convention on the Law of Treaties), it has come into effect under the international law, and the party is obliged to perform the matters it agreed with the other party. However, the Japan-US Agreement did not obtain the approval of the Diet as a treaty, and so whether or not it has effect in Japan depends on whether or not it was formed legally under the domestic laws.

Under the Constitution of Japan, the "treaty" that needs approval of the Diet (Article 73, Subparagraph 3 of the Constitution) means, irrespective of whether it is called a "treaty" or not,

(*10) For the details of the other measures taken, see Shigeo Takakura "Chiteki Zaisan Housei to Kokusai Seisaku (Legislation on Intellectual Property and International Policy)" p. 208 et seq. (Yuhikaku, 2001). Note that the full English text of the second agreement is quoted in Sumiko Kobayashi "Aratana Nichibei Tokkyo Goui ni okeru Ryuiten (Points to Be Noted in the New Japan-US agreement on Patents)" Patent, Vol. 47, No. 12, p. 69 (1994).

a legal agreement in writing on the establishment or change of the relations with a foreign country of rights or obligations in the international law. According to the opinion of the government clarified by the (then) Minister of Foreign Affairs Ohira in February 1974, included in those which do not need to obtain approval of the Diet are: ① "an international agreement that can be implemented within the range of a treaty which has already been approved by the Diet"; ② "an international agreement that can be implemented within the range of a budget which has already been adopted by the Diet"; and ③ "an international agreement that can be implemented within the range of domestic laws." Namely, according to the opinion of the government, the point at issue is whether or not the contents of the Japan-US Agreement can be judged to be an international agreement that does not need to obtain approval of the Diet.

Item ① and Item ② of the measures taken by the Japanese side are already reflected in the Patent Law by amendment, and so they do not seem to affect the domestic effect of the entire Japan-US Agreement. The problem lies in Item ③ of the same. Article 92 of the Patent Law is construed that, unless falling under the category of exceptional matters fixed by law, the Commissioner of the Patent Office is obliged to order a license to be granted, and such exceptional matters occur when "the grant of a non-exclusive license would unduly injure the interests of the other person ..." (Paragraph 5 of the Article). Therefore, such an interpretation was generated that the content of Item ③ of the Japan-US Agreement is within the range of discretion given to the Commissioner of the Patent Office to judge whether it falls under the category of Article 92, Paragraph 5 of the Law. (This interpretation is referred to as "Interpretation A".) Meanwhile, if Item ③ of the Japan-US Agreement is incorporated into Paragraph 5 of the Article, granting a non-exclusive license on the dependent invention unduly injure the interests of the other person, as a general rule, but in the case "to remedy a practice determined after judicial or administrative process to be anti-competitive or to permit public non-commercial use," exceptionally the grant would not injure them at all, or not "unduly" injure the same. That is to say, Paragraph 5 of the Article is a provision in which a license is not to be granted "as an exception," whereas upon applying Item ③ of the Japan-US Agreement thereto by the Commissioner of the Patent Office, it is transformed in nature into a provision in which a license is not to be granted "as a general rule." Thus Item ③ of the Japan-US Agreement transforms in nature the requirement to realize claim rights to request for an arbitration decision, and at the same time exceeds the range of discretion entrusted by legislation, and therefore is construed to be a "treaty" that needs approval of the Diet as "an international agreement containing legal matters." Accordingly at the present stage, the Japan-US Agreement has not come into effect domestically (which interpretation is hereafter referred to as "Interpretation B").

(2) Problems of the Japan-US Agreement

Where the Commissioner of the Patent Office has rendered a arbitration decision to reject a request for right of a non-exclusive license, based on the provisions of the Operational Instructions of the System of Compulsory License and Item ③ of the Japan-US Agreement, if a person having an objection thereto files an administrative litigation contending over the domestic effect of Item ③ of the Japan-US Agreement, asserting the illegality of the arbitration decision, then the plaintiff has the possibility to win the case in accordance with Interpretation B. This is because, Item ③ of the Japan-US Agreement, of which contents have been introduced on newspapers or magazines only and having no specific contents stipulated as a domestic law, is unlikely to become a jurisdictional norm. On the other hand, if a non-exclusive license is granted by an arbitration decision based on Article 92 of the Patent Law, notwithstanding the requirements in Item ③ of the Japan-US Agreement are not satisfied, then there arises a problem that it contravenes Item ③ of the Japan-US Agreement and is in violation of the international law.

Therefore under the present situation after the Japan-US Agreement, an amendment of the Patent Law to realize the contents of Item ③ of the Japan-US Agreement should be made. However, before doing so, it should be determined as the policy judgment of Japan in consideration of the requirements of the industrial sector in Japan and other circumstances, whether or not Item ③ of the Japan-US Agreement should be maintained.

3 Influence in the Case of the Contents of Item ③ of the Japan-US Agreement Having Been Put into Practice in Japan

As part of the material for making policy judgment as to whether the contents of Item ③ of the Japan-US Agreement should be put into practice in Japan hereafter, its influence at home and abroad when it has been put into practice in Japan is studied below.

(1) Limitation of Granting a Non-Exclusive License by an Arbitration Decision on the Dependent Invention

As an example of "anti-competitive practices" set forth in Item ③ of the Japan-US Agreement, such a case is assumed that, when the second patentee makes a proposal for granting a license with the first patentee, the first patentee demands the conditions of licensing that fall under an unfair trade practice, or rejects licensing. In addition, it

is also required to meet the requirement of Article 31, Subparagraph (1)(i) of the TRIPS Agreement (the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent). Examples that meet all of these requirements are very limited.

(2) Relation to the Compulsory License System for Public Interests

In the event that there arises a need of grantinga non-exclusive license on the first patent by an arbitration decision, even when lacking the requirements stipulated in Item ③ of the Japan- US Agreement, if the requirements in Article 93 of the Patent Law that reads "particularly necessary in the public interest" (hereinafter, referred to as "requirement of the public interest") are satisfied, then it is construed that a non-exclusive license can be granted by an arbitration decision.

When interpreting the requirements of the public interest, a theory on the constraint of property rights that is interpreted by Article 29, Paragraph 2 of the Constitution can serve as a reference. Namely, it is presumed that there is little objection to the interpretation that regulations for the purpose of preventing harm to lives and health, which are called the intrinsic constraint, satisfy the requirements of the public interest as set forth in Article 93 of the Patent Law(*11). In the meantime, different opinions would be given on the policy-related constraint.

The Article leaves the decision on suitability of granting a non-exclusive license based on an abstract requirement called the public interest to the discretion of the Minister of Economy, Trade and Industry. Therefore, whether or not the request in concern falls under the category of the public interest depends on whether granting a non-exclusive license by an arbitration decision is necessary and at the same time reasonable, in order to carry out the policy of patent administration employed at the time of rendering the arbitration decision, under the objectives stipulated in the Patent Law. In addition, it is construed that the contents of the public interest change according to the administrative purpose. Therefore, a comprehensive study needs to be conducted, taking into account the change in the industrial structure and diplomatic policy of Japan, as to whether a flexible interpretation of the requirements of the public interests may be of advantage to Japan.

(3) Influence on Domestic Industries

By applying Item ③ of the Japan-US Agreement, at the present time, those possessing many patents of basic inventions in Japan have advantages in the Japanese market, which is disadvantageous to those having improvement inventions only. In this regard, the pharmaceuticals industry, in particular, has pointed out that it is disadvantageous to Japanese businesses. In addition, (a) improvement inventions are often greater in development cost or economic value than basic inventions; (b) under the Japanese Patent Law which aims at the development of industries, such an idea is fundamentally inappropriate as to deem the former to be in a superior position to the latter; and (c) Japanese businesses are conventionally good at improvement inventions for industrialization, and it has also been pointed out that it is undesirable to deprive them of incentives therefor by adopting Item ③ of the Japan-US Agreement(*12). On the contrary, when turning our eyes into the future, it will be an incentive for the businesses to invest labor forces and research and development cost into fundamental research, with a view to obtaining patents of basic inventions instead of improvement inventions, rather than to conduct researches on putting basic inventions to use or on improvements.

Therefore, whether or not to execute the Japan-US Agreement is a matter as to which of basic inventions and improvement inventions/ practical inventions should be put emphasis on, and thus controls the industrial and technological policies of Japan in the future.

(4) Influence on Foreign Policies

The result of the revisions of laws in the U.S. based on the measures taken by the U.S. side according to Items ① and ② in the Japan-US Agreement is somewhat unsatisfactory to Japan. Therefore, Japan needs to continue requesting its improvements of the U.S. from now on. Besides, it is not only to the advantage for Japanese businesses but is the most important issue in terms of the harmonization of worldwide patent systems as well, that the U.S. will abandon its first-to-invent rule to shift to the first-to-file rule. Therefore, Japan is in the stage of requesting the U.S. strongly to make efforts for the harmonization of patent systems in coordination with Europe and other countries and regions, after having executed the Japan-US Agreement in good faith.

In the meantime, the industrial sector would also expect that Japan will request developing countries to control the abuse of compulsory licenses and to strengthen the protection of intellectual property rights, with a view to protecting its own industries as an industrialized

(*11) Therefore, in such a case in which a minimum compulsory license is granted to supply medicines that are indispensable for protecting the lives and health of the people, compulsory license based on Article 93 of the Patent Law would be justified irrespective of whether there is any relation of dependent inventions.

(*12) Shoji Matsui "Wagakuni Riyou Hatsumei no Saitei Jisshiken Seido no Kenkyu to Heisei 6 Nen no Nichibei Goui Dai 3 Kou no Igi (A Study of the Compulsory License System of Dependent Inventions in Japan and the Significance of the Japan-US Agreement in 1994)", Chizai Kanri (Intellectual Property Management), Vol. 51, No. 11, p. 1603 (2001).

nation. It is difficult to request other countries not to enforce compulsory licenses while positively carrying out granting non-exclusive licenses by an arbitration decision in Japan. The range of litigation and operation in Japan should also be determined, depending on to what extent Japan wishes to make requests on developing countries, namely, depending on whether it is construed as being sufficient to request them to observe the provisions of Article 31 of the TRIPS Agreement, or whether Japan wishes to request them further to abide by even the contents of the Item ③ of Japan-US Agreement, and also depending on to what extent non-exclusive licenses granted by an arbitration decision for the purpose of public interests can be permitted under Article 31 of the TRIPS Agreement.

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