Japan
Japon
Japan

Report Q202

in the name of the Japanese Group

The impact of public health issues on exclusive patent rights

Questions

I) Analysis of current law and case law

1) Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?

YES.

The Japanese Patent Law provides in Article 69 (1) that "A patent right shall not be effective against the working of the patented invention for experimental or research purposes."

Detailed explanation:

Meaning of Article 69 (1):
The purpose of the Patent Law is "to encourage inventions, and thereby to contribute to the development of industry" (Article 1). If a patent right were also effective against experiments and research intended for technological progress, it would prevent such progress and thus impede the development of industries. To achieve the purpose of the Patent Law, Article 69 (1) defines the working of the patented invention for "experiments and research" as a limitation of the patent right and thereby achieves a fair balance between the patentees' interests and the public interest.

Since a patent right is only effective against working of the patented invention conducted "as a business" (Article 68), Article 69 (1) only applies for the working of the patented invention conducted as a business for the purpose of experiments and research. Needless to say, a patent right is not effective against the working of the patented invention for the purpose of experiments and research that are not conducted as a business.

Interpretation of "as a business":
The Japanese Patent Law states that a patent right is not effective against working of the patent invention that is not conducted as a business in the first place. However, the details of working "as a business" are not specified in the Act, and there are not sufficient judicial precedents regarding the meaning of this statutory phrase. Thus the interpretation of "as a business" is left entirely to academic doctrines. In academic circles, the prevailing view is that the working of a patented invention "as a business" includes all activities except those not related to industrial activities, such as individual or domestic ones. The term "industrial activities" is not limited to activities conducted for profit or conducted strictly for the purpose of business, but includes all activities relating to business. In other words, working can be deemed as being "as a business" even if its direct purpose is not profit. Working of the patented invention conducted in the course of public work projects, medical service and legal practice is also considered to be working "as a business." According to this interpretation, it is

highly likely that the working of a patented invention for experiments and research conducted by universities, etc. will be regarded "as a business."

Interpretation of "experiment or research":

General interpretation of "experimental or research purposes" in Article 69 (1) of the Patent Law depends largely on academic doctrines since there are not enough judicial precedents.

In the prevailing doctrine, it is considered that whether or not an experiment or research falls within the scope of "experiment or research" exempted by Article 69 should be decided depending on its subject and purpose, and that an experiment or research should be regarded as falling within such a scope only when its subject is limited to the patented invention itself and when its purpose is limited to "technological progress" (e.g. patentability research, function research, experiment for improvement or development of the invention).

With regard to patentability research, etc., Keiko Someno, *Shiken Kenkyu ni okeru Tokkyohatsumei no Jisshi (Working of a Patented Invention for Experiments or Research)*, AIPPI, Vol. 33, No. 3, 5 (1998) explains as follows:

Patentability research
An experiment conducted to find whether another party's patented invention has novelty and involves inventive step, for the purpose of deciding whether or not it is possible to petition the for an invalidation trial or an opposition.

Functionality research
An experiment conducted to see whether another party's invention can be worked or has the effects as described in the description (in some cases, to verify whether the invention will bring about adverse side-effects). This type of experiments is conducted most often. It also includes experiments conducted for the purpose of ascertaining what economic advantage or disadvantage the invention has or deciding what costs will be required to put the invention into practice. It is sometimes conducted for the purpose of deciding whether the experimenting party should seek a licence for the patent.

Experiment for improvement/innovation
An experiment conducted for the purpose of improving another party's invention or creating a better invention. For working of an improvement invention arising from such an experiment (dependent invention), it is necessary to use the other party's invention and therefore to obtain a license from the other party. Once such a license has been agreed, the owner of the basic invention (the other party) will receive benefits from the use of the improvement invention. On the other hand, a "design-around" invention does not use the other party's invention. However, it is necessary even for such an invention to satisfy the requirements of novelty and inventive step in order to be patented. Therefore, an experiment for designing around another's invention will contribute to technological progress.

The Japanese Patent Law does not differentiate the working of another person's invention for profit from that which is not for profit. Therefore, the scope within which a patent right is effective does not differ depending on whether the patented invention is worked by a corporation (profit-making institution) or a university (non-profit institution).

2) *Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?*

NO.

The Japanese Patent Law has no "Bolar exception." In other words, it has no exception specially designed for clinical trials and other experiments for obtaining approval of production of generic products, exists in Japan. However, clinical trials and other procedures for generic products are exempted under Article 69 (1) of the Patent Law, which provides for limitation of patent rights for "experiments and research."

Detailed Explanation:

The Supreme Court decided on April 16, 1999 that the working of a patented invention for the clinical trials necessary to file an application for approval of production of a generic product falls under "experiments or research" exempted by Article 69 (1)." Thus, it can be said that the rule that a patent is not effective against the working of the patented invention for a clinical trial conducted to file an application for approval of production of a drug is established under case law.

The Supreme Court decision reaches the aforementioned conclusion by holding that:

1) If the clinical trials necessary to file an application for approval of production of a generic product are not permitted during the patent term, the third party will be unable to work the invention even after the expiration of the patent term.

2) The patentee can secure economic benefits through the exclusive use of the patented invention during the patent term.

This Supreme Court decision is made based on the regulation of the Pharmaceutical Affairs Act and it is construed that the scope of exemption covered by the decision includes patented inventions on drugs, quasi drugs, cosmetics with ingredients specified by the Minister of Health, Labor and Welfare, or medical devices for which approval of production under Article 14 (1) of the Pharmaceutical Affairs Law is required. In addition, it is considered that the scope of exemption also includes patented inventions on agrichemicals for which registration under Article 2 (1) of the Agricultural Chemicals Regulation Law is required. Biological products are also regarded as falling under medical drugs and are exempted from patent infringement liability as far as it is subject to control under the Pharmaceutical Affairs Law.

On the other hand, since exemption under the decision is limited to "the case where someone owns a patent right for a chemical substance or a medical drug that has the chemical substance as its active component," it thus seems that a research tool patent is not covered by the exemption. It is also construed that the applicability of Article 69 (1) to the working of a patented invention for a research tool is likely to be denied in the case where the subject of research is not the patented invention itself, under the aforementioned prevailing academic doctrine.

3) Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?

NO.

The Japanese Patent Law has no specific provisions regarding parallel imports of patented products.

Detailed Explanation:

In Japan, It was traditionally considered that importing a patented product which is legally distributed in a foreign country and assigning it in Japan was an infringement of the patent right. However, a Supreme Court decision on July 1, 1997 (Case No. Heisei 7(wo)1988) held that in the case where the owner of a patent in Japan sold a patented product outside Japan, the patent owner should not be allowed to enforce its patent in Japan against the assignee of the patented goods or subsequent acquirers who acquired the patented product from the

asignee, unless the assignee explicitly agrees to exclude Japan from the place of sale or use of the patented products and a notice of such an agreement is clearly indicated on the patented product. The Supreme Court decision indicated that its conclusion was not derived based on the exhaustion doctrine, by clearly stating that the conclusion would be the same regardless of whether the patentee has a foreign patent in the country where the patented product was originally assigned. Instead, the Supreme Court cited the necessity of protecting the assignee's confidence in free distribution as the rationale for prohibiting the exercise of the Japanese patent right on the parallel-imported patented products. Such a necessity arose from the fact that the transaction in the foreign country was made on the assumption that the assignee obtained (and was implicitly given) all rights that the assignor had (including the right to import the product into Japan). In other words, the Supreme Court Decision was rendered based on implicit license doctrine.

Parallel imports of genuine patented products need to satisfy the following requirements to avoid the exercise of Japanese patent rights:

a) The product must be assigned in a foreign country by the patent owner or a person who can be regarded as a person equivalent to the patent owner;

b) There is no agreement between the assignee and the patent owner to the effect that Japan is excluded from the place of sale or use of the product;

c) A notice of such an agreement is not clearly indicated on the patented product.

Therefore, it is possible for the patentee to assert infringement of the patent right and breach of the agreement against the assignee's act of importing the product into Japan if the agreement is made as specified by (b) above, and the notice is clearly indicated on the product as specified by (c). This rule is considered to apply not only to pharmaceuticals, medical devices or the like, but to all products.

From this, we can conclude that importation of products produced in a foreign country under a compulsory license to Japan could not allowed, since. g the compulsory license will be generally ordered to satisfy the domestic demand of that foreign country and will thus restrict the place to which the products manufactured thereunder may be sold to that country.

Furthermore, Japan has accepted the Protocol amending the TRIPS Agreement and is obliged to ensure the availability of effective legal means to prevent the importation into, and sale in, its territory of products produced under the system provided for in the protocol and diverted to its market inconsistently with the protocol's provisions, using the means already required to be available under the TRIPS Agreement (including injunction).

4) Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?

YES.

The Japanese Patent Law provides that a patent right for the invention of a process to manufacture a medicine by mixing two or more medicines shall not be effective against the act of preparation of a medicine as is written in a prescription from a physician or a dentist and the medicine so prepared.

Article 69 (Limitations of patent right)
3) A patent right for the invention of a medicine (refers to a product used for the diagnosis, therapy, treatment or prevention of human diseases, hereinafter the same shall apply in this paragraph) to be manufactured by mixing two or more medicines or for the invention of a process to manufacture a medicine by mixing two or more medicines shall not be effective against the act of preparation of a medicine as is written in a prescription from a physician or a dentist and the medicine prepared as is written in a prescription from a physician or a dentist.

5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?*

No answer to this question is needed.

Detailed Explanation:

In Japan, the "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body" are regarded as an "industrially inapplicable invention" under the JPO's "Examination Guidelines for Patent and Utility Model," and are not patentable.

6) *Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.*

YES.

The Japanese Patent Law does not use the term "compulsory license," but it has a system of "award granting non-exclusive license," which plays the same role as a compulsory license under certain conditions. The Patent Law provides the following three types of awards of non-exclusive license,[1] which have been in place since the former Patent Law enacted in 1921.

1) Award granting non-exclusive license where the invention is not worked (Article 83)
2) Award granting non-exclusive license of the basic invention to work a dependent invention (Article 92)
3) Award granting non-exclusive license for public interest (Article 93)

However, as of February 2008, there has been no case where any of the above awards were granted.

Detailed Explanation:

1) Award granting non-exclusive license where invention is not worked
   A person intending to work a patented invention may request its patentee or its exclusive licensee to hold consultations to discuss granting a non-exclusive license for the patented invention after four years have lapsed from the filing date of the patent application for the invention, if the patented invention is not sufficiently and continuously worked for three years or longer in Japan. Where there is a legitimate reason for the failure to sufficiently work the patented invention, however, the Director General of the Patent Office shall not award a non-exclusive license.
2) Award granting non-exclusive license to work own patented invention
   Where a patented invention uses another party's patented invention, registered utility model, or registered design (or design similar thereto) for which a patent application or an application of registration was filed prior to the date of filing of the application for said patented invention, or where the patent right for a patented invention is in conflict with another person's design right or trademark right obtained based on an application filed prior to the date of filing of the application for said patented invention (Article 72), the patentee or exclusive licensee of the patented invention may request the other person to hold consultations to discuss granting a non-exclusive license to work

[1] see Berline Shikkoiinkai no Gidai ni taisuru Nihonbukai no Iken (2) (Gidai 187: Haitateki (Dokusenteki) Chitekizaisanken no Kyosoho ni yoru Seigen (AIPPI Japan's Opinion on Questions on the Agenda at Executive Committee Meeting in Berlin (2) (Q187: Limitations on Exclusive IP Rights by Competition Law), AIPPI Vol. 50, No. 3, 164-165(2005).

the patented invention or a non-exclusive license for the utility model right or the design right (Article 92(1)). The rightholder of the basic invention (the other person's invention) may request the patentee or exclusive licensee requesting such consultations to hold consultations to discuss granting a non-exclusive license to the extent of the patented invention that said patentee or exclusive licensee intend to work under the non-exclusive license for the other party's patent right (Article 92(2)). Where no agreement is reached through the consultations or no consultations can be held, the other party may request the Commissioner of the Patent Office for an award granting such a non-exclusive license.

3) Award granting non-exclusive license for public interest
A person intending to work a patented invention may request its patentee or its exclusive licensee to hold consultations to discuss granting a non-exclusive license on the condition that "the working of a patented invention is particularly necessary for the public interest."

In any of the above three cases, consultations between the parties are to be held first. Where no agreement is reached through consultations or no consultations can be held, a non-exclusive license may be awarded by the Commissioner of the Patent Office (Article 83 and Article 92) or the Minister of Economy, Trade and Industry (Article 93) upon the request of the person intending to work the patented invention. Even after a non-exclusive license is awarded, it may be cancelled upon the request of an interested party or by the Commissioner's own authority, if the person to whom the non-exclusive license was granted fails to work the patented invention properly.

With regard to the non-exclusive license for public interest mentioned in (3) above, *"Saitei Seido no Unyo youryo (Instructions on Implementation of the System of Awarding Non-Exclusive Licenses)"* issued by the Industrial Property Council defines "cases where the working of a patented invention is particularly necessary for the public interest" as "(i) cases where it is particularly needed in areas relating directly to the lives of citizens, such as the areas of public health, asset protection and construction of public facilities, or (ii) cases where the sound development of the relevant industry will be damaged if a non-exclusive license for the patented invention is not granted, and as a result, substantial damage will be caused to lives of citizens." It is interpreted that the word "particularly" is used for the purpose of strictly limiting the applicability of the requirement of "non-exclusive license for public interest," and if there are any alternate means to protect the public interest other than awarding a non-exclusive license for the patent in question, a non-exclusive license cannot be awarded even if the costs of these alternate means would be higher than in the case where a non-exclusive license for the patent was awarded.

A report published by the Foreign Investment Council's Expert Committee in 1968 put forward its view that a non-exclusive license may be awarded even for the sake of the national economy, by stating: "A non-exclusive license under Section 93 of the Patent Law may be allowed when the patent is regarded as being important for areas relating directly to the lives of citizens, such as the areas of public health, protection of assets and construction of public facilities. It may also be allowed when substantial adverse effects on the national economy are likely to occur due to the following events arising as a result of the monopolization of an important patented invention that is necessary for the production of certain products or is related to the implementation of certain industrial processes: (i) It is feared that a huge number of people will be made unemployed due to bankruptcy or other disruptions occurring for a corporation that is expected to use the patented invention; (ii) it is feared that, through bankruptcy or other disruptions occurring for corporations in a certain industry that are expected to use the patented invention, a huge amount of existing facilities in the industry, which would be utilized if the industry could use the patented invention, is likely to be destroyed; and (iii) when bankruptcy or other disruptions occur for corporations in a key industry, important export industry or hi–tech industry that is expected to use the patented invention, the sound economic or technological development of the industry is likely to be substantially hindered."

The provisions for awarding a non-exclusive license were introduced in the Patent Law for the following reason. For the non-exclusive license for non–working invention mentioned in (1) above, it is because patents could not contribute to the development of domestic industries if they were not used appropriately. The provisions for awarding a non-exclusive license to work one's own patented invention mentioned in above (2) above were stipulated to encourage improvement invention. Both of them were considered to contribute to the original purpose of the patent system. In addition, at the time of enactment, these provisions were considered to promote technology transfer from advanced nations. The provisions for non-exclusive license for public interest stated in (3) above were adopted in order to provide a remedy for situations where the public interest was harmed by the adverse effects of exclusive rights given to patents. However, unlike the former Patent Law, which provided for the restriction, expropriation or cancellation of patent rights as a measure for providing such a remedy, the current Patent Law attempts to achieve this purpose only by allowing the competent authorities to give an award to force a patentee to grant a non–exclusive license.

It seems that any of the three non-exclusive licensing schemes can be justified by the necessity of ensuring free competition. In particular, according to the aforementioned criteria (ii) for awarding a non–exclusive license for the public interest in the *Instructions on Implementation of the System of Awarding Non-Exclusive Licenses*, it can be understood that the term "public interest" in Section 93 of the Patent Law means the interests of businesses and consumers, and that a non-exclusive license may be granted when the exclusive patent right has the effect of limiting or precluding competition.

In any case, a party that has received an award may, if unsatisfied with the amount of compensation determined in the award, institute an action demanding an increase or decrease of said amount. (Article 183 of the Patent Law).

7) *Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.*

YES.

Japan accepted the Protocol amending the TRIPS Agreement on August 31, 2007. However, Japan does not need any new legislative measures to implement the protocol, and thus no legal revisions have been made. There have not been any cases where a compulsory license (award of non-exclusive license) has been exercised for the import or export of medical drugs.

8) *Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?*

NO.

There is no provision in the Japanese Patent Law that makes it possible for any party (even the government) to implement a patented invention without obtaining the license.

Detailed Explanation:

As described in 6) above, although the former Patent Law had provisions to expropriate or cancel a patent right if the public interest is particularly damaged as an adverse effect of monopoly through a patent right, the current Act permits only the awarding of a non-exclusive license.

9) Is the government allowed to expropriate a patent and, if so, under which conditions?

NO.

Detailed Explanation:

See the answer to question 8) above.

10) If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.

NO.

Detailed Explanation:

There are no means other than the ones mentioned in the answers to questions 1) through 9) above.

II) Proposals for adoption of uniform rules

1) Should patent law provide for

– *research and experimental use exception;*
It should not necessarily require every country to provide this exception in their patent laws. The policies given in the resolution for Q105 (except for 4) adopted by the Tokyo World Congress in 1992 should be followed, if this exception is introduced to any patent laws.

– *Bolar exception;*
It should not necessarily require every country to provide the Bolar exception in their patent laws. In the case of a country that provides the research and experimental use exception in its patent law, the Bolar exception should be given in the provision on research and experimental use or through interpretation of such a provision. If a country decides to provide in its patent law to the effect that a patent is not effective against the working of the patented invention for a clinical trial conducted to file an application for approval of production of a generic drug, production of only the quantity required for the trial should be allowed. It should not be allowed to produce the patented medicines for the purpose of production and storage with the intention of selling them after the date of expiration of the patent.

– *parallel import of patented medicines;*
It should not require every country to provide permissibility of such parallel importation in their patent laws. If a country introduces such a provision in its patent law, it should not allow this parallel importation on the grounds of international exhaustion, as noted in the resolution for Q101 adopted by the Melbourne Executive Committee in 2001.

– *individual prescriptions exception;*
It seems acceptable to require every country to provide such an exception in their patent laws, since medical composition is a patentable subject matter under the TRIPS Agreement. However, it is necessary to provide the definition of individual prescription first.

– *medical treatment defence;*
Such a defence should be allowed in countries where a medical treatment method is patentable. However, it should not require every country to adopt this defence since most countries do not allow a patent on a medical treatment method.

– *compulsory licensing;*
It seems acceptable to require every country to provide a compulsory licensing scheme,

but it should be provided within the scope of the TRIPS Agreement and the Protocol amending the TRIPS Agreement, in a manner consistent with the direction indicated in the resolution on Q187 adopted by the Executive Committee in Berlin in 2005. Since if a globally uniform system for compulsory licensing is to be established within the framework of patent law, it should be designed within the TRIPS Agreement and the Protocol amending the TRIPS Agreement, the first thing to do is discuss the issue of access to medicines – which is the underlying issue of this question (Q202) – in the General Council and to effectuate and implement the Protocol amending the TRIPS Agreement, which was prepared in December 2005 and achieves a fair balance between incentives for the development of new useful products or processes and the public interest in limiting the scope of patent rights. Therefore, a resolution should be made to prompt member states to accept the protocol without delay.

– *expropriation;*
  It should not require every country to provide expropriation in their patent laws, since there are some countries, such as Japan, where expropriation is not allowed.

– *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*
  It should be neither established nor obliged.

If so, under what circumstances? If not, why not?

Countries have different legal structures: some adopt a statute law system and others adopta common law system. Thus, for the purpose of establishing globally uniform rules, it seems sufficient if substantially similar action will be taken on the same issue under the legal systems of respective countries. In addition, these limitations on patents may be provided by acts other than the Patent Law. In any case, since these limitations are exceptions to patent rights to be established to protect public health, they should ensure a fair balance between incentives for the development of new useful products or processes and third party interests, and their scope should be narrowly defined and construed. They should basically be provided in accordance with the policies underlying the relevant provisions in the TRIPS Agreement.

2) *Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

No.

3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*

Many countries have limitations of patent rights under their statutory provisions or case law. However, the scope of these differs by country. (Inventions relating to public health have unique characteristics in that products produced based on these inventions may be put on the market only after the regulatory authorities examine them from the viewpoint of safety and grant approval for their manufacture or sale. On the other hand, the situations surrounding public health issues vary greatly among countries depending on what systems – for example, systems based on private practice and free competition, official price systems for pharmaceuticals, systems requiring all nationals to be covered by public health insurance – are adopted, what authorities and powers are given to the regulatory authorities, the level of the country's competence in developing new pharmaceuticals, the level of medical treatment in the country, the country's fiscal condition, etc.)

Although it would be ideal if patent laws around the world were harmonised in this respect, it seems difficult to achieve this given the current status of WIPO negotiations on the Substantive Patent Law Treaty (SPLT). This is because the issue of the relationship between patents and

public health cannot be discussed without linking it to the issue of access to medicines in developing countries and least developed countries. In fact, it has been proposed in the SPLT negotiations that not only the harmonization of substantive aspects of the patent granting process but also the harmonization of issues such as compulsory licensing, technology transfer and the limitation of patent rights should be discussed in the framework of the SPLT, and the negotiations have not made much progress. We believe that the attempt to harmonize issues such as the research and experimental use exception, Bolar exception and individual prescriptions exception should first be started at the meeting of Group B+ member states or another similar forum consisting of developed countries.

Regarding this issue, it should be noted that the development of new medicines has come to require higher costs and longer-term research due to the more stringent safety criteria of regulatory authorities. In such circumstances, if the limitations of patent rights expand and the incentives for development are impeded, there is a possibility that it would stifle research and development activities in the pharmaceutical and other related industries, which would ultimately harm the interests of consumers. The patent system is designed to give incentives for the development of new useful technologies, and any limitation of patent rights should be provided in an exceptional and limited manner. The issue of access to medicines is, in its very nature, an issue that lies outside of patent law and should be discussed at an appropriate forum such as the WHO.

Summary

1) The Japanese Patent Act specifies that a patent right shall not be effective against the working of the patented invention for the purpose of "experiments and research." However, there are no widely-accepted criteria for judging what activities fall under the "experiments and research" category, due to there being insufficient judicial precedents. As a result, in order to make such a judgment, one has to rely on academic theories developed in the late 1980s, which is before we started to face the issues of the "experiments and research" exception and Bolar exception. Although said Act lacks a provision corresponding to the "Bolar exception" rule, clinical trials and other experiments for the production of generic products are exempted by the Supreme Court under a general provision that limits patent rights for "experiments and research."

2) The Japanese Patent Act has no specific provisions about parallel imports of patented products. There is a judicial precedent where the Supreme Court prohibited the exercise of a patent right on the grounds that the patentee had implicitly assigned all of its rights to the assignee, who purchased the patented goods from the patentee outside Japan. It should be noted that this judgment was not made based on the patent exhaustion doctrine, which aims to prevent patent owners from "double-dipping."

3) The Japanese Patent Act provides that a patent right for the invention of a process to manufacture a medicine by mixing two or more medicines shall not be effective against the act of preparing a medicine according to a prescription written by a physician or a dentist, or against the medicine so prepared.

4) The Japanese Patent Act has a provision effective as a compulsory license under certain conditions, but not under the term "compulsory license," but "discretionary license" (Article 93). Although several petitions were filed in the past, such discretionary license has never been ruled for issuance.

5) Japan accepted the Protocol amending Article 31bis of the TRIPS Agreement on August 31, 2007. Japan does not need to take any new legislative measures for the implementation of the protocol. In Japan, there are no precedents where a compulsory license (discretionary

license) was issued for the import or export of medical drugs. The Japanese Patent Act does not explicitly permit any party, even the government, to exploit a patented invention without a license.

6) Since the patent system is designed to give incentives for the development of new useful technologies, any restrictions on patent protection should be limited in terms of scope and applicability. Having too many restrictions on patents would reduce scientists' incentives to conduct research and development and consequently harm consumers' interests. Regarding the availability of medicine, most of the associated issues are unrelated to patent law. These issues should be discussed further at WHO meetings and other appropriate occasions.

Résumé

1) La loi sur le brevet japonaise spécifie que l'effet de droit de brevet ne s'étend pas sur la mise en exécution des inventions brevetées dans le but de "l'examen ou la recherche". Cependant, vue la jurisprudence sur l'interprétation générale de "l'examen ou la recherche" qui n'est pas encore assez accumulée, l'interprétation de cette disposition reste fondée sur la doctrine issue de l'ère où les problématiques de l'exception de "l'examen ou la recherche" et de l'exceoption Bolar ne se sont pas encore produits, c'est-à-dire de la seconde moitiée des années 1980. Il n'y a pas de disposition qui correspond à l'exception Bolar et les sujets tels que l'examen clinique des médicaments génériques sont traités comme des problématiques relatives à l'application des dispositions générales sur "l'examen ou la recherche" suivant la jurisprudence de la Cour suprême.

2) Aucune disposition concrète concernant l'importation parallèle de produits brevetés n'est établie. Or, la jurisprudence de la Cour suprême restreint l'effet de droit de brevet du cédant, parce que le transfert du droit de brevet est une transaction qui implicitement accorde au cessionnaire tous les droits détenus par le cédant dans les commerces économiques à l'étranger. Mais il faut noter que cette décision n'est pas une décision basée sur la doctrine d'épuisement, qui nie le double profit.

3) Une disposition stipule que l'effet de droit de brevet relatif à l'invention de méthodes pour fabriquer des médicaments en mélangeant plus de deux médicaments ne s'étend pas aux actes des médecins ou dentistes pour préparer des médicaments selon l'ordonnance et aux médicaments résultant de ces actes.

4) La loi sur le brevet japonaise établit une disposition portant sur la "licence non-exclusive par arbitrage" (non pas la "licence forcée") qui accorde, sous certaines conditions, un effet similaire à la licence forcée. A cet égard, il y a eu des requêtes de la licence non-exclusive par arbitrage dans le passé, mais aucune décision n'a été rendue au Japon.

5) Le Japon a accepté le protocole modifiant l'article 31-2 de l'Accord sur les ADPIC au 31 août 2007. Une nouvelle mesure législative n'est pas nécessaire pour la mise en vigueur de ce protocole. Or la licence forcée (licence non-exclusive par arbitrage) n'a jamais été accordée pour l'importation ou l'exportation de médicaments. En outre, la loi sur le brevet japonaise ne permet même pas au Gouvernement de réaliser l'invention brevetée sans avoir obtenu la licence.

6) Le système de brevet vise à fournir une incitation au développement technique et la restriction du droit de brevet doit rester rigoureusement exceptionnelle et limitative. Au cas où la restriction du droit de brevet se développe et que l'incitation ne suffit pas, la recherche et le développement seraient abandonnés et il en résulte des désavantages pour les consommateurs. Le problème d'accès aux médicaments est d'ailleurs en grande partie un problème autre que celui du droit de brevet et par conséquent, l'OMT ou d'autres organisations responsables doivent approfondir la discussion.

Zusammenfassung

1) Das japanische Patentrecht regelt ausdrücklich, dass der Patentschutz im Falle einer Benutzung patentierter Erfindungen zu „Forschungs- und Versuchszwecken" nicht wirksam ist; allerdings gibt es für eine allgemeine Auslegung dessen, was unter „Forschungs- und Versuchszwecken" zu verstehen ist, noch keine ausreichende Zahl von Präzedenzfällen, und die Auslegung dieser Bestimmung beruht auf einer Lehre aus der zweiten Hälfte der 1980er Jahre, also aus einer Zeit vor dem Ausnahmeregelung für „Forschungs- und Versuchszwecke" bzw. dem Problem der „Bolar-Ausnahme". Es existiert keine der „Bolar-Ausnahme" entsprechende Regelung; bei klinischen Versuchen von generischen Arzneimitteln usw. finden nach einer Entscheidung des Obersten Gerichts die allgemeinen Bestimmungen bezüglich „Forschungs- und Versuchszwecken" Anwendung.

2) Es existieren keine konkreten Regelungen zum Parallelimport patentierter Produkte. Zwar liegt ein Urteil des Obersten Gerichts vor, nach dem es sich bei im Ausland getätigten Geschäften um Geschäftsakte handelt, bei die vollständige Abtretung der gesamten Rechte des Abtretenden impliziert ist; dabei handelt es sich jedoch nicht um ein erschöpfendes Urteil gegen doppelten Profit.

3) Die Gültigkeit des Patentrechts im Zusammenhang mit Verfahrenserfindungen, bei denen ein Präparat durch Vermischen von zwei oder mehr Präparaten hergestellt wird, erstreckt sich nicht auf das Zubereiten von Präparaten auf Rezept durch einen Mediziner bzw. auf in dieser Weise entstandene Präparate.

4) Das japanische Patentgesetz kennt keine „Zwangslizenz", wobei allerdings Bestimmungen existieren, nach denen durch eine nicht-exklusive Lizenzierung unter bestimmten Bedingungen dasselbe Resultat wie bei einer Zwangslizenz erzielbar ist. Zwar wurden bereits solche nicht-exklusive Lizenzierungen beantragt, doch ist bislang kein Bescheid tatsächlich erteilt worden.

5) Zum 31. August 2007 hat Japan das Änderungsprotokoll für Artikel 31bis des TRIPS-Übereinkommens übernommen; daraus ergab sich allerdings kein Bedarf an neuen legislativen Massnahmen. Es wurden bisher keine Zwangslizenzen (nicht-exklusive Lizenzen) zum Import oder Export von Arzneimitteln erteilt, und das japanische Patentrecht verfügt über keinerlei Bestimmungen, die die Ausübung einer patentierten Erfindung ohne Lizenzerwerb ermöglichen würden, auch nicht durch die Regierung.

6) Das Patentsystem dient der Förderung der technischen Entwicklung, weshalb eine Einschränkung von Rechten in jedem Fall eine begrenzte Ausnahme bleiben sollte. Eine weitere Einschränkung der Patentrechte bedeutet geringere Entwicklungsanreize, wodurch die Forschungstätigkeit zum Erliegen kommt; dies wirkt sich letztlich negativ auf den Verbraucher aus. Der Kern der Frage des Zugangs zu Arzneimitteln liegt nicht im Patentsystem, und wir hoffen, dass eine weitere Eingrenzung der Diskussion im Rahmen der WHO sowie an anderer geeigneter Stelle stattfinden wird.