Q238

Second Medical Use or Indication Claims

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Questions

I. Current law and practice

Groups are invited to answer the following questions under their national laws. If those national and regional laws apply to a set of questions, please answer the questions separately for each set of laws.

Please number your answers with the same numbers used for the corresponding questions.

1) Does your country permit patents covering any aspect of new uses of known pharmaceutical compounds (hereafter referred to as second medical use claims)?

(Answer)

Yes.

If yes, please answer Questions 2) to 7) inclusive before proceeding to the questions in Parts I and II. If no, please proceed directly to the questions in Parts II and III.

2) If the answer to Question 1) is yes, please answer the following sub questions.

a) What is the basis for patent protection?

(Answer)

Article 29(1) of the Japanese Patent Act provides "Any person who has made an invention which is industrially applicable may obtain a patent therefor, except in the case of the following inventions:

The invention here means "an invention of a product," "an invention of a process," and "an invention of a process of manufacturing a product" (Article 2).

The Patent and Utility Model Examination Guidelines published by the Japan Patent Office (Part II, Chapter 1, Section 2.1) identify a "method of surgery, therapy or diagnosis of humans" as not industrially applicable. Therefore, a second medical use claim may be patented so long as it is not claimed as a "method of surgery, therapy or diagnosis of humans."

The Guidelines (Part VII, Chapter 3 "Medicinal Inventions") explicitly state that a medicinal invention based on a second medical use is "an invention of a product." Incidentally, the following instructions are found in other part (Part I, Chapter 1, Section 2.2.2.3) of the Guidelines:

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"Use" is interpreted as a term meaning a method for using things which is categorized into "a process." (e.g. "Use of substance X as an insecticide" is interpreted as "method for using substance X as an insecticide." Also, "Use of substance X for the manufacture of a medicament for therapeutic application Y" is interpreted as "method for using substance X for the manufacture of a medicament for therapeutic application Y.")

According to the JPO's practice, a patent may be granted to even a Swiss-type claim or a claim in which a second medical use is identified in a method of manufacture, provided the other requirements are met. In fact, there exist many Japanese patents involving such types of claims.

In the enforcement phase, however, such Swiss-type use claim or method of manufacture claim often gives rise to a controversy over the scope of protection. Therefore, it is considered advisable to claim such an invention as a product according to the Japanese practice. For this reason, we answer the questions hereinafter on the assumption that a second medical use is claimed as a product.

b) What types of second medical use are patentable? See, for example, paragraphs 14) - 17) above/WGLs.

(Answer)

According to the Examination Guidelines, second medical use inventions are broadly classified into two types:

One type is a pharmaceutical invention related to a known compound. A pharmaceutical invention which relates to a second medical use or which is intended for a different disease may be patentable. This corresponds to 15) WGLs.

The other type is a pharmaceutical product that uses the same active component as an existing drug for the same indication, but with a particular dosage and/or administration method. If such dosage and/or administration produces a striking effect beyond expectation of the one skilled in the art, then this invention may be patentable. This second type corresponds to 17) WGLs.

c) Are any types of second medical use impermissible subject matter? See, for example, paragraphs 14) - 17) above/WGLs.

(Answer)

There is no type of second medical use that is impermissible as a subject matter.

d) What forms of second medical use claims are permissible? See, for example, paragraphs 26) - 33) above/ WGLs.

(Answer)

A typical permissible claim would be "a pharmaceutical for treatment of disease Y comprising compound X." Other examples include "a disease Z drug," "a composition for treatment of disease Y," and "a treatment kit for disease W."

A claim which identifies a combination of two or more active ingredients, and one which identifies a manner of

treatment such as an administration interval and dosage are permissible. A Swiss-type claim is also permissible. Moreover, a method of manufacture claim is also permissible. For example, "a method for manufacturing a pharmaceutical product using an ingredient extracted from humans."

e) What forms of second medical use claims are not permissible? See, for example, paragraphs 26) - 33) above/WGLs.

(Answer)

A method of operating on, treating or diagnosing humans is not permissible, for example:

> "A method of treating a patient suffering from disease Y comprising: administering an effective amount of compound X to the patient."

A claim directed to "use of compound X for treatment of disease Y" is also interpreted as a method-of-treatment claim and therefore not permitted.

A claim directed to "compound X for treatment of disease Y" may not be patentable due to lack of novelty when compound X has already been know. This is because such a claim can be interpreted as directed to compound X itself, not to the use qualified by "for treatment of disease Y."

f) Has any guidance been provided by courts or the national patent office in relation to the meaning, scope and/or effect of 'treatment', 'treating' or 'use to treat' integers in second medical use claims? See, for example, paragraphs 34) - 39) above WGLs.

(Answer)

It seems that a use invention for "treatment" of a particular disease does not have a technical scope that extends beyond this use, according to the following court precedent:

In a case of infringement on a patent claim which reads: "a preventive agent for allergic asthma containing ketotifen or pharmaceutically acceptable acid addition salt as an active ingredient," the court held that the technical scope of this invention does not cover other uses than the clamed use "prevention of allergic asthma" (Tokyo District Court decision dated 23 October 1992, case No. 1990 (Wa) 12094).

3) If your country permits second medical use claims:

a) Who may be liable for infringement of such claims? For example:

- **i) the party marketing the drug with label instructions which describe the patented use;**
- **ii) the physician prescribing the drug for such use;**
- **iii) the pharmacist dispensing a drug for such purpose;**
- **iv) the patient using the drug for such purpose?**

(Answer)

i) A party who manufactures, markets, or imports the drug (with label instructions which describe the patented use) is liable for infringement (direct infringement).

ii) A physician who prescribes the drug for the patented use may be liable for infringement (the Japanese Patent Act does not provide for exemption of liabil-

ity for physicians).

iii) A pharmacist dispensed the drug for the patented use may be liable for infringement, except the case of an invention of mixed drug (Article 69(3) of the Patent Act, which is the only provision for exemption of liability under the Act).

b) Are any parties exempt from infringement or liability for infringement of such claims? If so, what classes of party?

(Answer)

Physician and pharmacist: *A patent right for the invention of a medicine to be manufactured by mixing two or more medicines or for the invention of a process to manufacture such a medicine shall not be effective against the act of preparation of a medicine as is written in a prescription...* (Article 69(3) of the Patent Act)

Patient: using the drug for such purpose does not constitute the use of the patented invention "in business" (Article 68 of the Patent Act) but a personal use.

c) Are such claims enforceable on the basis of direct or indirect infringement? Please provide details.

(Answer)

Yes. A second medical use claim is enforceable on the basis of direct or indirect infringement.

The act of manufacturing, marketing, importing etc. of the drug with label instructions which describe the patented use constitutes a direct infringement.

Even without label instructions which describe such use, the act of manufacturing, marketing etc. of the drug may constitute a contributory infringement of the second medical use claim, when done with the knowledge that it will be used for the patented use (Article 101(ii) of the Patent Act).

4) If a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, is it an infringement if a party makes, supplies or uses a generic version of the drug for any use?

(Notes)

If "for any use" means "whatever the use is," our answer would be "No." If you are asking whether the above-mentioned act constitutes an infringement when intended "for a use of a certain kind," our answer is as follows:

(Answer)

The above-mentioned act will be found infringing only when a party makes or supplies a generic version of the drug to be intended for use defined in the patent claim, or he/she uses it for such purpose.

A typical example: if a generic product is approved for a use that falls within the claims of a patent and its package insert refers to such use, this generic product will be determined to be an infringing product that is "made or supplied to be intended for such use" (Tokyo District Court decision dated 23 October 1992, case No. 1990 (Wa) 12094)

According to another precedent, a generic product may be found infringing even if its package insert does not directly and explicitly refers to such use, but if the patentee proves that it is "made or supplied to be intended for such use"

based on a set of specific and objective facts (IP High Court decision dated 21 November 2006, case No. 2005 (Ne) 10125).

5) If the answer to Question 4) is yes, please answer the following sub questions in that context.

a) Is each of the acts of making, supplying and using a form of infringement? If not, please specify which (or any other) acts which constitute infringement.

(Answer)

The acts of making and selling a product to be used for a use that is specified in the claims of a patent and the act of using the product for such use each constitute infringement (Article 2(3)(i) of the Patent Act).

b) Is it necessary for a finding of infringement that the party making, supplying or using the generic version of the drug does so in connection with the infringing use?

(Notes)

We have carefully analyzed the questions, but we are not sure how "infringing use" can be different from "working (execution) for the patented use." If you use these phrases for different meanings from each other, unfortunately we do not understand your intention.

The reason for this is as follows. Under the Patent Act of Japan, a way of working for the patented use is differentiated whether "the use" is done "commercially (as a business)" or not. The "infringing use" in Question 5 c) may not be interpreted as meaning "used commercially." In Japan, for a finding of infringement, the use of an invention needs to be done "commercially" (Article 68 of the Patent Act).

Although we do not fully understand your usage of the phrases as noted above, we would like to answer the questions to the extent possible. We answer the following questions on the basis of the assumption that "infringing use" is interchangeably used with "for the patented use."

(Answer)

Yes. In order for us to have a court to recognize making, supplying or using of a generic product should be "infringing use," namely, it needs to be done for the patented use.

If a certain act is found infringing regardless of its use (whether it is infringing use), this would be virtually equivalent to a situation where there is a patent on the relevant substance (compound).

As described in Q 4) above, the act of infringing use (making or supplying a generic product to be intended for the patented use or using it for such purpose) typically refers to a case where a generic product is approved for a use that falls within the claims of a patent and its package insert refers to such use. (Tokyo District Court decision dated 23 October 1992, case No. 1990 (Wa) 12094)

According to another precedent, a generic product may be found infringing if its package insert does not directly and explicitly refers to such use but the patentee proves that it is "made or supplied to be intended for such use" based on a set of specific and objective facts (IP High Court decision dated 21 November 2006, case No. 2005 (Ne) 10125).

c) If yes to b), is it necessary that the party knows that their actions are in connection with the infringing use?

(Answer)

The party's knowledge that "their actions are in connection with the infringing use (the patented use)" does not need to be argued or proved in itself.

Instead, it is necessary to argue or prove that the product is "made or supplied to be intended for such use" or "used for such purpose" based on a set of specific and objective facts. (However, when such an argument or proof is accepted, the alleged infringer probably knows that his/her action has been done for such purpose.)

(1) Specifically, the patentee could prove that the infringing product was "made or supplied to be intended for the patented use" if marketing authorization was granted from the Ministry for such use and the package insert referred to such use (Tokyo District Court decision dated 23 October 1992, case No. 1990 (Wa) 12094).

(2) In another case, the package insert did not refer to such use, but the court found that the product was "made or supplied to be intended for such use" based on a set of specific and objective facts or the party's external acts:

> The party promoted the medicinal agent in question by actively characterizing it by its pharmacological effect for which marketing authorization has not been granted and marketed a certain percentage of the products to be intended for the patented use. (IP High Court decision dated 21 November 2006, case No. 2005 (Ne) 10125)

(3) There has not been a case where, without any external acts as described in (2) above, the court recognized that the product was "made or supplied to be intended for the patented use." However, such a case is possible, for example:

> A use patent held by an originator company has expired for a Use X but continues in force for a Use Y. If a generic company makes and markets a generic drug by obtaining a marketing authorization for the Use X (a "carved-out" generic drug), there will be a question as to whether this act of the generic company infringes the originator's use patent that is in force for the Use Y.
>
> In this hypothetical case, the generic company knows that its product also has efficacy for the Use Y, but a conclusion cannot be reached only by virtue of this knowledge. The question is whether the court would find that the product is "made or supplied to be intended for such use" when the patentee proves, in some way, the understanding among those skilled in the art (healthcare professionals) about the demand for the generic company's product for the Use Y, percentage of the preparations allocated to the Use Y, and usefulness of the Use Y. Therefore, the conclusion would depend on specific circumstances.

(4) Finally, if a very small number of people use a pharmaceutical product for its patented use to conduct a special research, but they are not aware that they

use it for such purpose, it is unlikely that the court will hold that the product is "made or supplied to be intended for such use."

In fact, there has not been a case where the court found that a patent was infringed when the alleged infringer did not know that the product in question was (would be) intended for the patented use.

So far, we have discussed direct infringement.

In relation to contributory infringement, there are two types of product: an "exclusively-used" product and an "indispensable" product. Article 101(ii) of the Patent Act provides for an indispensable product as follows:

> *Where a patent has been granted for an invention of a product, acts of producing, assigning, etc., importing or offering for assignment, etc. any product (excluding those widely distributed within Japan) to be used for the producing of the said product and indispensable for the resolution of the problem by the said invention as a business, knowing that the said invention is a patented invention and the said product is used for the working of the invention;*

For a finding of contributory infringement in relation to this type of products, it is necessary that the party makes or markets his/her product "knowing" that it is connected with the infringing use (patented use).

d) If yes to c), what standard of knowledge is required? See, for example, paragraphs 38) and 47) above.

(Answer)

In relation to a use invention, the party's knowledge that "their actions are in connection with the infringing use (the patented use)" does not need to be argued or proved in itself (see our answer to Q 5c) above).

However, for a finding of contributory infringement in relation to an "indispensable product," it is necessary that the party (alleged infringer) know that "the said invention is a patented invention and the said product is used for the working of the invention."

Without such knowledge, the party's act does not constitute an infringement even if it is due to negligence. The reason why an act caused by negligence is not included in the acts of contributory infringement is said to be the following:

> If a component has two or more intended uses, it would be hard for the component suppliers to be obliged to check how these components are used by their clients. Such obligation also could seriously affect the security of transactions (*Commentary on Industrial Property Law* 19th edition, published by the JPO).

As to the acts mentioned below, however, it is not necessary, for a finding of contributory infringement, that the party (alleged infringer) know that "the said invention is a patented invention and the said product is used for the working of the invention":

> *the act of producing any product to be used exclusively for manufacture of the generic product in business* (Article101(i) of the Patent Act); and
> *the act of possessing the said product to be assigned or exported in business* (Article101(iii)).

6) How do the courts determine infringement of a second medical use claim? What are the legal tests and evidentiary requirements?

(Answer)

See our answer to Q 4) above.

As described in Q 5c) above, according to the Japanese practice, the party's knowledge that "their actions are in connection with the infringing use (for the patented use)" does not need to be argued or proved in itself, except for certain cases of contributory infringement.

7) What relief is available for infringement of a second medical use claim:

a) at a preliminary / interim / interlocutory level?
b) by way of final relief?

(Answer)

Injunctive relief is available both at a) preliminary level (preliminary injunction) and b) by way of final relief (permanent injunction). In Japan there is no argument that such relief should not be available to medical use claims or to second medical use claims. Actually, there are several cases where the court granted a permanent injunction in infringement proceedings related to second medical use claims.

According to a court precedent, the scope of injunctive relief (including preliminary injunction and permanent injunction) is limited to the product (preparations) intended for a use of the invention and does not extend to the compound contained as the active ingredient:

Tokyo District Court decision dated 23 October 1992, case No. 1990 (Wa) 12094 (*Chiteki Saishu* vol.24 No.3 page 805; *Hanrei Jihou* No.1469 page 139). The name of a second medical use invention: "a preventive agent for allergic asthma containing ketotifen or pharmaceutically acceptable acid addition salt as an active ingredient. The court did not grant an injunction against the use of "fumarate compound (ketotifen fumarate) expressed as the chemical formula in the left column..." which is the active ingredient for a pharmaceutical product. The court granted an injunction only against the marketing of the pharmaceutical product for periodic and continued use (containing ketotifen fumarate as its active ingredient; indicated for treatment of bronchial asthma, asthma, and allergic asthma; administered orally twice a day: after breakfast and at bedtime). As of 25 May 1992, its product names were: "Zaditoma Capsule" (defendant: Kyowa Pharmaceutical Industry Co., Ltd.); "Ketotilon Capsule" (defendant: Ohara Pharmaceutical Co., Ltd.); and "Saldimen Capsule" (defendant: Tatshumi Kagaku, Co., Ltd.).

(See also our answer to Q 5) above.)

8) In respect of Question 7)a), can a preliminary / interim / interlocutory injunction be granted solely upon the statements provided in the product packaging or based on the writing of a prescription? If not, what is the basis for relief?

(Answer)

According to the Japanese practice, a preliminary injunction may be granted solely upon the "statements provided in the product packaging" or the "writing of a prescription (package insert)" if they refer to the patented use, which will be

considered as sufficient evidence on "uses of invention." (Although the decision of case No. 1990 (Wa) 12094 was on a permanent injunction, it is applicable to the case of a preliminary injunction.)

As to proof of the sufficiency on other constituent elements than "uses of invention," the package insert describes the active ingredients, their content, etc. and therefore, any other evidence is often not necessary for these elements.

According to the current practice in Japan, in order that the court may find evidence sufficient on the constituent elements, the required level of firm belief is the same in both cases of preliminary and permanent injunctions. Consequently, it is not the case in Japan that a preliminary injunction may be granted based on less evidence as compared to a permanent injunction. In fact, there have been very few cases where a preliminary injunction was granted in advance of a permanent injunction in patent infringement cases. (It is possible, of course, to seek a preliminary injunction alone.)

The reason for such practice in Japan is that a request for preliminary injunction against patent infringement is handled in *inter partes* proceedings where an argument of the other party (alleged infringer) is always heard. Since the other party often asserts reasons for insufficiency and defense of invalidity, the same level of arguments and evidence are provided as in the case of a permanent injunction, which is allowed by the court. Therefore, if a patentee files requests for both preliminary and permanent injunctions around the same time, both proceedings will be carried out in parallel. In this respect, there is a big difference from those countries where *ex parte* proceedings are carried out.

Since "necessity of preservation" is a requirement for a preliminary injunction, there are more facts to be proved formally for the grant of a preliminary injunction than a permanent injunction. However, there have been very few decisions that reject a request for preliminary injunction in patent infringement cases due to the denial of "necessity of preservation." (e.g. If a generic company has started a procedure to obtain approval under the Pharmaceutical Affairs Act, it is highly likely that the court recognizes the necessity of preservation.)

In the decision of case No. 1990 (Wa) 12094 mentioned above, a claim in the original specifications said, "an agent for prevention or treatment of allergic symptoms..." but the patented invention was "a preventive agent for allergic asthma."

Therefore, for the grant of an injunction against each of the defendants' products, the plaintiff needed to argue and prove that each of the products was "a preventive agent for allergic asthma," not "a treatment agent for allergic symptoms."

In the decision, the court evaluated the details of the package inserts and concluded, "each of the defendants' products is 'a preventive agent for allergic asthma' as claimed in the patent. This is not an agent to be administered to a patient who has an acute attack of allergic bronchial asthma, but is an agent to be periodically and continuously administered to prevent a patient with a diagnosis of asthma from having an attack. Consequently, this product is determined to be an agent for preventing an acute attack of allergic bronchial asthma.

In this decision, the court determined the sufficiency of evidence on "uses of

invention" solely based on the package inserts of the defendants' products.

(See also our answer to Q 5) above.)

9) In respect of Question 7)b), what level of proof is required to obtain a final injunction?

(Answer)

According to the Japanese practice, as described above, evidence on "uses of invention" may be found sufficient based on the product information leaflet if it refers to the patented use, and a permanent injunction may be granted (case No. 1990 (Wa) 12094).

If the party has not obtained approval under the Pharmaceutical Affairs Act for an effect/efficacy of the drug in the patented use and the package insert does not refer to such use, but the patentee can prove that it is marketed to be intended for such use by off-label prescription, then evidence on "uses of invention" will be sufficient.

For example, the IP High Court's decision (21 November 2006, case No. 2005 (Ne) 10125) says, "Generally, to exploit a use invention of a drug, the patentee obtains approval under the Pharmaceutical Affairs Act for an effect/efficacy of the drug in such use. In the case of a medical use patent, however, a mere act of marketing the drug to be intended for such use may constitute exploitation of the invention, whether with or without approval under the Act. Even though such an act of marketing may be against the Act in some way, this should be considered as exploitation of the invention, as long as the party actually markets the drug to be intended for such use. Typically, the patentee exploits a use invention of a drug by manufacturing or marketing the drug with its label or packaging that directly and explicitly refers to the patented use. Even without such direct and explicit indication, however, if it is apparent, under certain circumstances, that the drug is marketed to be intended for such use, exploitation of the invention may be equally proven. As stated above, cilostazol, the active ingredient of the patented medicinal agent, is widely recognized as a medicinal agent for prevention of restenosis after PTCA. The appellee promoted the drug by actively characterizing it as being effective for prevention of restenosis and marketed a certain percentage of the products to be intended for the patented use. For this reason, it is found that the appellee exploited this use invention."

Incidentally, in the United States or other countries where common law and equity coexist, there are equitable requirements to be met for grant of an injunction (both provisionary and permanent) in addition to sufficiency of evidence (e.g. U.S. Supreme Court decision on the *eBay Inc.* case).

In Japan, an injunction (both provisionary and permanent) is traditionally granted when evidence on the constituent elements (including "uses of invention") is found sufficient. This holds true for second medical use inventions. Although there is debate over whether a request for injection may be rejected for public interest reasons, no precedent exists for this issue at this time.

II. Policy considerations and proposals for improvements to your current law

10) If your country permits second medical use claims, please answer the following sub questions.

a) What are the policy reasons behind permitting such claims?

(Answer)

As part of amendments to the Patent Act in 1975, Japan introduced the system for substance patents and abolished a provision under which pharmaceutical inventions were not eligible for patent protection. In preparation for this amendment, the Industrial Property Council conducted hearings for academic experts and related industrial circles.

From the viewpoint of public interests, the Council decided, "pharmaceutical patents will not have adverse effects on people's lives because there are many types of similar pharmaceutical products available in the market these days."

The pharmaceutical industry commented, "Since the prohibition of chemical and pharmaceutical patents is one of the factors that have brought about technical gaps, we hope that these gaps will be gradually closed after lifting of the prohibition."

There was no discussion, in particular, on whether there should be a distinction between the first and second medical uses. Prior to the introduction of the substance patent system, use inventions were already accepted for other than pharmaceutical and food uses, without distinction between the first and second uses. Partly because of this situation, it seems that there was no special reason for distinction between the first and subsequent medical uses.

It was found recently that an invention of a medicine characterized by its dosage and/or administration method (including cell/tissue-based medicine) is eligible for patent protection. According to a report dated 29 May 2009 by the Advanced Medical Patent Review Committee, a reason behind this change is as follows:

The Committee that was set up the Cabinet Office discussed the following:

(i) Importance of dosage and administration method to a drug,
(ii) Needs of the public and importance of incentive measures
(iii) Adequacy of a system where a pharmaceutical invention of a new dosage and/or administration method is protected as an invention of "a product," and
(iv) Impact on burden of expenses and free access to patients.

After the discussions, the Committee reached the following conclusion:

"It is important to promote R&D of drugs that may dramatically reduce the occurrence of side effects or greatly improve the quality of life (QOL) of patients, through the renovation of dosages and/or administration methods. To expand the availability of these drugs, it is necessary to provide protection to pharmaceutical inventions of new dosages and/or administration methods that achieve greater effect than expected by the experts. This type of inventions should be protected as an invention of "a product," and to this end, the Examination Guidelines should be revised by taking into consideration presented specific examples."

b) Are such claims as are currently permissible in your country considered to strike the right balance between the interests of relevant stakeholders?

(Answer)

Basically, a generic version of the drug is equivalent to its originator drug in the effect or efficacy. In Japan, it is allowed to obtain marketing authorization for a generic by "carving out" the patented indications from its product information, which serves as a prevention of "ever-greening" of originator pharmaceutical patents. For this reason, we think that second medical use claims help strike a good balance between the originator and generic manufacturers in our country.

As with an invention of a pharmaceutical composition, a second medical use invention is useful and it is the fruit of considerable time and effort. The lack of patent protection would allow free riders to exploit second medical uses and discourage the developers, against the intent and purpose of the patent system that is to promote inventions.

c) Is it considered that such claims better serve the interests of some stakeholders and/or are detrimental to other stakeholders?

(Answer)

As described in b) above, patent protection for second medical use inventions is not conducive to "ever-greening," and therefore, not detrimental to any stakeholders at all. On the contrary, such protection may encourage the originator pharmaceutical companies to establish new therapeutic uses of their existing pharmaceutical products by making a considerable investment in additional clinical development. As a result, such protection may hopefully provide benefit in the future to patients suffering from disease without a cure.

d) If there is any empirical or anecdotal data available, please address the following.

i) What is the prevalence of second medical use claims in your country?

(Answer)

Since we cannot find any objective data or means used to study second medical use claims separately from other claims, we are not sure about the prevalence of second medical use claims in Japan. However, our answer to ii) below provides some information on patents that contain second medical use claims in certain technical fields.

ii) What is the profile of patentees for second medical use claims in your country?

(Answer)

Utilizing the use of "F-term," the JPO's original system for classifying Japanese patent documents, we conducted a brief study of the profile of patentees of second medical use inventions in Japan. Note that the results shown below are rough data because it was difficult to exactly identify second medical use patents and categorize their patentees into groups.

IPC: A61K31/00-31/327 (Medicinal preparations containing organic active ingredients, excl. heterocyclic compounds). F-term 4C206 AA01 is assigned

to a patent application that has a medical use claim for a medicine containing an acyclic or carbocyclic compound.

IPC: A61K31/33-33/44 (Medicinal preparations containing organic active ingredients such as heterocyclic compounds, and medicinal preparations containing inorganic active ingredients). F-term 4C206 AA01 is assigned to a patent application that has a medical use claim for a medicine containing other organic and inorganic compounds.

IPC: A61K35/00-35/76 (Medicinal preparations containing material or reaction products thereof with undetermined constitution). F-term 4C087 AA01 is assigned to a patent application that has a medical use claim for a medicine containing material from animals or micro-organisms.

IPC: A61K37/00-37/66, 41/00-45/08, 48/00 (Medicinal preparations containing protein materials, lipoids or derivatives thereof, medicinal preparations containing other active ingredients etc). F-term 4C084 is assigned to patent applications that cover medicines containing protein lipid enzymes and other bio-medicines.

IPC: A61K35/78-35/84 (Materials from plants). F-term 4C084 is assigned to patent applications that cover medicines containing plant substances.

These five F-term categories do not cover all second medical use inventions but you can see an overall trend of the patentees of such inventions.

For classification by therapeutic activity of medicinal preparations, the JPO also uses the sub-class A61P (specific therapeutic activity of chemical compounds or medical preparations) of the IPC 8th edition.

As second medical use patents, we studied those patents that are categorized into IPC A61P and correspond to one of the F-term codes 4C206 AA01, 4C086 AA01, 4C087 AA01, 4C088, and 4C084. The number of applications for second medical use patens that have been filed since 1 January 2000 is 27,070.

We classified these 27,070 patents by type of patentees: 9,589 originator and 1,862 generic pharmaceutical companies (314 of them are classified as both originator and generic companies).

4,446 patents are held by 85 domestic originator companies (52 of them are members of the Japan Pharmaceutical Manufacturers Association (JPMA) and the remaining 33 are not JPMA members).

5,372 patents are owned by 39 foreign originator companies (20 of them are JPMA members and the remaining 19 are non-members). (Note that a domestic subsidiary of a foreign company is counted as a foreign company.)

On the other hand, 1,725 patents are held by 66 domestic generic companies (35 of them are members of the Japan Generic Medicines Association (JGA) and the remaining 31 are not JGA members.

179 patents are owned by 45 foreign generic companies (4 of them are JGA members and the remaining 41 are non-members). (Note that a company that belongs to both the JPMA and the JGA is counted as a JPMA member.)

1,012 patents are owned by patentees whose names include “university” and two of them are also classified as originator and generic pharmaceutical companies.

From these results, we conclude: it seems that approx. a third of the patentees of second medical use patents are originator pharmaceutical companies, a fifteenth of them are generic companies, and a

thirtieth are universities. Although the results may vary depending on how they are classified, foreign originator companies hold more second medical use patents than domestic originator companies. On the other hand, domestic generic companies hold more second medical use patents than foreign generic companies.

11) If your country does not permit second medical use claims, please answer the following sub questions.

a) What are the policy reasons behind not permitting such claims?
b) Would such claims serve the interests of relevant stakeholders?
c) Would such claims be considered to better serve the interests of some stakeholders and/or be detrimental to other stakeholders?

12) To what extent does your country's law in relation to second medical use claims affect the pharmaceutical industry (originator and generic) in your country?

(Answer)

According to the Japanese practice, a medical use invention basically needs to be identified as an invention of "a product." Therefore, it is difficult to grant a right to such an invention by identifying its technical aspect directly (or in a straightforward manner) as "a process," which is the essential part of the invention. For this reason, it is possible that the perception of the subject matter of a patent in the process of examination at the patent office may be different from the perception of it during proceedings before the court.

Consequently, we can say that a second medical use patent poses a potential risk for unnecessary disputes between a person (patentee) who enforces his/her right and a person (third party) who is affected by the enforcement of rights (e.g. an invention of a method for combined use of two or more medicinal agents). Since it is possible that there will be new types of second use inventions in the future, patent protection may not be provided adequately to such inventions under the current restrictions where a use invention basically needs to be represented in the form of a product (thing).

III. Proposals for harmonisation

The Groups are invited to put forward proposals for the adoption of harmonised laws in relation to second medical use claims. More specifically, the Groups are invited to answer the following questions *without* regard to their existing national laws.

13) Is it desirable to permit second medical use claims?

(Answer)

Undoubtedly, it takes considerable effort and cost to develop second medical uses. Since such an invention serves the public interest, it seems worthwhile to promote the development by offering an incentive in the form of grant of patents. For this reason, we think it is desirable to permit second medical use claims.

14) Is harmonisation of laws relating to second medical use claims desirable?

(Answer)

Pharmaceutical inventions have a

huge economic impact and related patent applications are often filed in many countries in the world. We think that international harmonization of laws is desirable from the viewpoint of improvement of predictability of inventors (applicants) and promotion of the development of second medical uses.

15) Please provide a standard that you consider to be best in each of the following areas relating to second medical use claims.

a) Types of second medical use constituting permissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

(Answer)

The types of second medical use mentioned in Q 2b) above should be permitted. These uses are not easily conceived from known technologies and serve the public interest. We think it is worthwhile to promote the development these uses by offering an incentive in the form of grant of patents.

b) Types of any second medical use constituting impermissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

(Answer)

We do not think there are any types of second medical use that should not be permitted as a subject matter.

c) Form of permissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

(Answer)

The forms of claim described in Q 2d) above, "a drug for treating disease Z," "a composition for treatment of disease Y," and "a treatment kit for disease W" should be permitted because they do not have any negative aspects, in particular. In addition, a method of operating on, treating or diagnosing humans, e.g. "Use of compound X for treatment of disease Y" described in Q 2e) should be permitted to the extent that health-care professionals are not hindered from freely working on operation, treatment and diagnosis.

d) Form of impermissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

(Answer)

It is desirable that a Swiss-type claim be impermissible, because its scope of protection is not clear.

e) Who may be liable for infringement?

(Answer)

When taking the following as an example of second medical use claim: "a pharmaceutical composition for treatment of disease xx containing an active ingredient A," a party who manufactured, marketed, or imported said pharmaceutical product (intended for the patented use described in its label instructions) may be liable for infringement.

f) Any parties/institutions that should be exempted from infringement or liability for infringement.

(Answer)

If a patent right extends to the use or prescription of the drug that is part of

treatment by the physician or to the pharmacist's act of dispensing it, they will be hindered from freely engaging in their healthcare activities. Therefore, the physicians, pharmacists, other healthcare professionals and medical institutions for which they work (hospitals, clinic, pharmacies, etc.) should be exempted from infringement or liability for infringement. Personal use by a patient should also be exempted from infringement.

g) Where a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, the acts that should constitute patent infringement, and in particular, the standard of knowledge of the alleged infringer.

(Answer)

If a certain act may be found infringing regardless of its use, this would be virtually equivalent to a situation where there is a patent on the relevant substance (compound). A party should be liable for infringement only when he/she makes or supplies a generic product to be intended for such use as defined by the patent claim, or he/she uses it for such purpose. A typical case is where the generic product is approved for a use that falls within the claims of a patent and its package insert refers to such use. If the package insert does not refer to such use, but it is apparent, from the party's external acts, that the product is "made or supplied to be intended for such use" or "used for such purpose," infringement should be found. In such a case, from the existence of the disclosed patent, it should be presumed that the party's acts are carried out intentionally or negligently and the party should be liable for infringement regardless of whether he/she knows that his/her actions are in connection with the infringing use. Furthermore, if the party makes or markets any product (except for those products that are in wide circulation in the market) that is used for the production and indispensable for solving the technical problems based on the invention, with the knowledge that it is used for such purpose, he/she should be liable for infringement, or contributory infringement, at least.

h) Relief available upon a finding of infringement:

i) at a preliminary / interim / interlocutory level; and
ii) by way of permanent relief.

(Answer)

Injunctive relief should be available both at a preliminary level (preliminary injunction) and by way of final relief (permanent injunction). In both cases, however, arguments of the alleged infringer should be heard.

i) In each case for h)i) and h)ii), the level of proof for the granting of such relief.

(Answer)

Even in proceedings for provisional disposition, the same level of proof should be required as compared to ordinary patent infringement litigation, and there is no reason, in particular, for mitigation of burden of proof. In the case of a second medical use patent, however, if "statements provided in the product packaging" or the "writing of a prescrip-

tion (package insert)" refer to the same active ingredient and the use (including an administration method, etc.) as in the patent claims, infringement may be found solely based on these documents and relief may be provided.

In addition, it is apparent, from the alleged infringer's external acts (e.g. his/her general knowledge of the drug, advertising activities and promotional efforts targeted for medical institutions etc), that the product is "made or supplied to be intended for such use" or "used for such purpose," infringement should reasonably be found.

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