Selected Articles from

YUASA AND HARA

INTELLECTUAL PROPERTY NEWS

VOL. 17 July 2005

CONTENTS

Court Case Review (Trademark)
Refilling of ink bottle for a printer-likelihood of confusion
(Tokyo District Court. January 21, 2003)
(Tokyo High Court. August 31, 2004)

1. Introduction

Refilling of ink bottles exclusively for use with printers manufactured by another party may constitute a trademark infringement.

Appellant (plaintiff): RISO Kagaku Corporation

Appellee (defendant): TAKKEN Corporation

Appellee (defendant): CORONA Giken

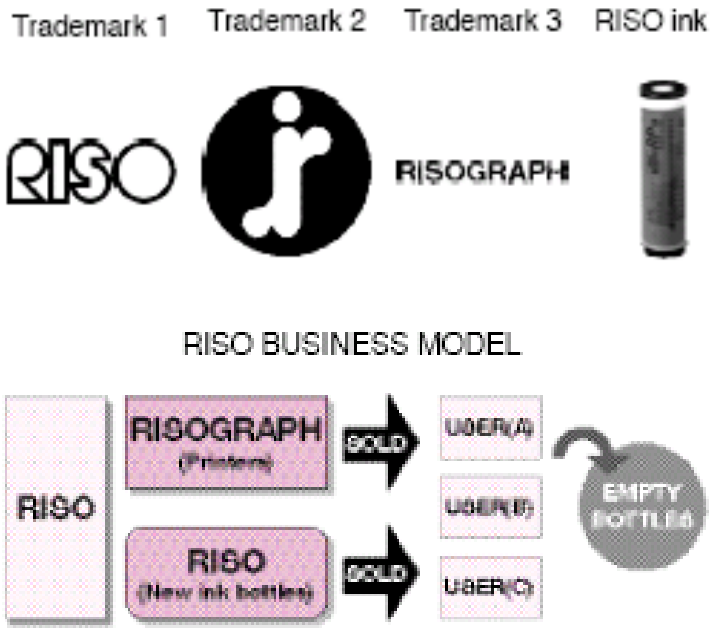
The mimeograph printing machine sold under RISOGRAPH by the plaintiff, RISO, was used with a specially designed ink bottle manufactured by the plaintiff, which was inserted into the applicable portion of the printing machine. The following registered trademarks of the plaintiff appeared on the ink bottles:

Trademark 1: Reg. No. 4091781 “RISO”

Trademark 2: Reg. No. 4091782 “RI figure”

Trademark 3: Reg. No. 4036757 “RISOGRAPH”

Goods covered: Printing inks, etc.



The defendants, TAKKEN and CORONA, filled up used ink bottles (empty containers) with ink produced by them and sold them to about 1500 customers, such as government offices, municipal offices, schools, financial institutions, etc., the users of the printing machine manufactured by the plaintiff. One of the defendants, Takken, was substantially the sales section of the defendant, Corona. Since the plaintiff’s registered trademarks remained on the ink bottles, the plaintiff sought an injunction against defendant’s displaying the plaintiff’s marks on the ink bottles, and an order for discarding of the ink bottles; and claimed damages, noting that defendants’ act infringed on the plaintiff’s trademark rights.

2. The findings of the Court

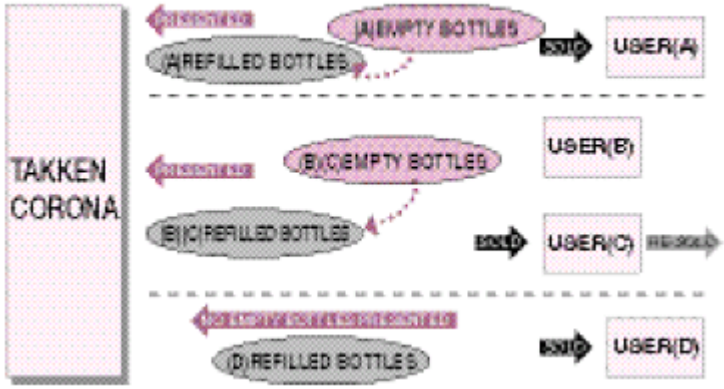
(1) In Heisei 14 (WA) 4835, Tokyo District Court denied the defendants’ trademark infringement, finding as follows:

FINDING OF DISTRICT COURT

When the defendants sold the ink for mimeograph printing, customers handed over empty ink bottles to the defendant Takken or the defendant Corona's local agents and subsequently, the defendant Corona filled up the empty ink bottles with the ink they had manufactured. The defendants without fail printed original lot numbers and the customer names on all the empty ink bottles so that each ink bottle could be returned to the original owner of the bottle after refilling. The bottles so refilled were returned to the customers by the defendant Takken or the defendant Corona's local agents. Since the plaintiff's registered trademarks appeared on the ink bottles when their customers presented them to the defendants to have them refilled with the defendant's ink, it was apparent and clear that the registered trademarks appearing on the ink bottles were not associated with the ink refilled by the defendant. Under these circumstances, there was no room for the trademarks to function as an identifier of the source of the goods, and thus there was no trademark infringement.

(2) The plaintiff filed an appeal with Tokyo High Court.

FINDING OF HIGH COURT



In Heisei 15 (NE) 899, the high court first noted that after washing empty ink bottles presented by customers, Corona filled them up with their manufactured ink and attached caps, thus storing them as finished goods.

The high court further found that there were two different manners of the appellees' selling their products as follows:

> The first manner was, as the district court had found, the situation where the appellees received used ink bottles (empty containers) from the users of the appellant's printing machine, filled them up with their produced ink and then delivered them to the customers as their products. However, Corona was dealing with as many as 1500 customers through Takken and many other local agents, and it was hardly possible to conceive that the ink bottles collected from their customers were in fact returned to the original and respective owners of the bottles in these large-scale dealings.
>
> The second type of the appellees' dealing was that where customers did not own any used and empty ink bottles, ink bottles under storage were delivered to them.

Before reaching conclusion, the high court examined the appellees' actual business transactions quite carefully and emphasized the following facts:

> (i) On the promotional literature, order forms and the like the appellees used in promoting and selling their products, the names and trademarks of the appellant's printing machines and ink bottles for use with the printing machines were displayed in the original formats. On the other hand, no such denial indication that the ink contained in the bottles was not manufactured by the appellant was shown in the literature. Rather, there was an indication likely to suggest that the ink filled by Takken in the ink bottles was that of the appellant.
>
> (ii) The appellant's registered trademarks remained to be displayed on the ink bottles for delivery to their customers in which the appellees' ink was filled and no denial indication was provided on the bottles.
>
> (iii) In some instances, not only those who actually were to use the ink in companies but people handling purchasing commodities in fact did not precisely realize that the ink contained in the bottles was supplied by the appellees, not by the appellant.
>
> (iv) The appellees' customers who purchased the ink bottles refilled by the appellees frequently re-sold the bottles to other parties.

3. Conclusion of the Court

On the basis of the above analysis, it was determined that the appellees' act of selling their ink obviously misled purchasers to assume that the ink refilled in the bottles on which the appellant's trademarks appeared came from the appellant and caused confusion as to the source of the products.

Tokyo High Court concluded that the appellees' act substantially injured this function of the appellant's trademarks and amounted to a trademark infringement.

In finding an infringement, the high court not only examined the situation carefully, but provided an opinion different from that of the district court. However, this analysis seems to suggest that the conclusion would have differed, had the defendants used an appropriate notice on the ink bottles that the ink was produced by them, not by the original manufacturer identified by the trademarks.

Kazuhiro Nakata (Mr.);
Patent Attorney of the Trademark & Design Division

Establishment of the Examination Guidelines in Japan for Medical Invention

1. Introduction

In April 2005, the JPO newly established "The Examination Guidelines for Medicinal Invention" as third Examination Guidelines, in Part VII: Examination Guidelines for Inventions in Specific Fields, which follow the item Computer Software Related Inventions and Biological Inventions. The new Guidelines apply to all pending applications filed on or after July 1, 1995, and those which are examined on or after April 15, 2005. In this Article, an explanation of contents of the new Examination Guidelines will be presented.

(1) Background

Under the Japanese patent practice, it has been commonly considered that an invention relating to a so-called "medical act" which is conducted by a physician, such as an invention of a method for treating, diagnosing or operating on a disease in a human, is not industrially applicable, and therefore, is not a patentable subject matter (Japanese Patent Law Art. 29(1), main paragraph). Further, in Japan, a second medical use of a compound has been protected as a pharmaceutical

composition or a therapeutic agent with a defined medical use (rather than as “a method of treating”) and a method of diagnosing has been substantially protected as a diagnostic product.

In August 2003, The Japan Patent Office (JPO) revised the Examination Guidelines for an industrially applicable invention to expand patentable subject matters relating to a medical act to include those which had not previously been deemed patentable. Specifically, it was decided that a method for preparing a medicament (such as a blood preparation, vaccine, recombinant preparation) or a medical device (such as artificial replacements or substitutes for parts of the human body such as an artificial bone and a cultured skin cell sheet) which are prepared using a human derived material as a raw material should exceptionally be regarded as a patentable subject matter under Japanese patent practice, even if the method is aimed at processing human body derived materials, assuming that they are to be injected or transplanted back into the same person for therapeutic purposes.

Further, it was also decided that a method for internally controlling a medical device, wherein a function of a medical device is expressed as a method and which does not exceed a process of control within the device, is a patentable subject matter. For a more detailed explanation regarding the revision of the Examination Guidelines made in August 2003, please refer to an article authored by Mr. Fukazawa, a patent attorney of Yuasa and Hara (YUASA AND HARA, IP NEWS, Vol.13, pages 17-20, published in January 2004).

(2) Movement for expanding patentable subject matter related to medical act

Although the Examination Guidelines for industrially applicable inventions were revised in August 2003, an industrially applicable, thus patentable, subject matter regarding a medical-related act is limited only to an invention of pharmaceuticals and a method for preparing thereof, an ex vivo method for treating biological materials, and a method for internally controlling a medical device. In order to meet the needs to enhance the industry's incentives for promoting the development of advanced medical technology and to sustain a competitive environment of global standard in Japan, particularly comparable to what is found in the United States, a number of measures have been proposed for amending the Japanese Patent system along the lines of the U.S. system, in which a medical-related act including “a method of treating” is considered as a patentable subject matter, and, on the other hand, acts performed by a physician should be discharged.

With regard to this proposition, as a further process following the revision of the Examination Guidelines in 2003, a Task Force on the Protection of Patents of Medical-Related Acts was set

up in a Strategic Council on Intellectual Property the matter has been under study from October 2003.

The Task Force carried out a general study of issues relating to the protection of medical-related acts as a patentable subject matter. However, the conclusion was that "there is a sparse necessity to protect a technique relating to an act conducted by a physician (for example, method of surgery and method for injecting, which should be conducted by a physician) as a patentable subject matter". And finally, it determined to further study possibilities to protect "a method for expressing novel potency and effect of medicines for manufacturing and selling medicines" and "a method for operating a medical device", which are not patentable subject matter under the existing Examination Guidelines.

The Task Force made an Arrangement on the Protection of Patents of Medical-Related Acts in November 2004. The Task Force arrived at a conclusion that in the case of a technique relating to "a method for expressing novel potency and effect of medicines for manufacturing and selling medicines", which is identified as a technique specified by a combination of two or more medicines or a treatment mode such as the dose interval and the dosage, reasonably best possible efforts should be made to expand the scope of protection as product patent by taking into consideration the problems of patent right validity in other fields and previous patented instances of medicinal inventions. The Task Force further concluded that such techniques should be protected as product patents and this should be clarified in the Examination Guidelines. However, it was also concluded that "techniques relating to an act conducted by a physician" should remain a non-patentable subject matter as before.

(3) Establishment of the new Examination Guidelines for Medicinal Invention

On the basis of the above conclusions, the JPO in April 2005 newly established "The Examination Guidelines for Medicinal Invention" (hereinafter referred to as the new Examination Guidelines (or merely, the new Guidelines)). The new Guidelines clarify that the medicinal inventions specified by a combination of two or more medicines and a treatment mode such as a dose interval and a dosage are "industrially applicable inventions" for it is an invention of a "product".

It should be noted that, the conclusions of the Task Force may be understood as suggesting the expansion of patentable subject matter relating to medicinal invention, however, the JPO has actually been following a practice of allowing medicinal invention specified by a combination of medicines or a treatment mode. Thus, patentable instances regarding medicinal inventions are

not substantially expanded by the new Guidelines. However, since the existing Guidelines do not stipulate requirements regarding such inventions, the new Guidelines make these points clear.

On other hand, as for a medicinal invention, criteria of judgment with regard to requirements for written description and enablement and the others are described in isolated sections of the existing Examination Guidelines. In addition, although the patent practice on medicinal inventions involves special judgments and handlings, not all of them were clearly stipulated in the existing Guidelines. In view of these problems, the new Examination Guidelines are established in order to clearly lay down the criteria of judgment with regard to requirements for novelty, inventive step, written description and enablement, etc. and to clarify the judgments and the handlings of a medicinal invention.

In this Article, an explanation of contents of the new Examination Guidelines will be presented. Especially, the new Guidelines relating to medicinal invention specified by a combination of two or more medicines and a treatment mode such as the dose interval and dosage is explained in detail.

Besides, as for "a method for operating a medical device", the Task Force concluded in the Arrangement that such a method should be taken as a patentable subject matter. The Japanese Patent Office, by taking this into consideration, in April 2005 revised the Examination Guidelines for industrially applicable inventions to include patentable subject matter relating to "a method for operating a medical device". As for the explanation regarding the revision, please refer to a separate article of this issue co-authored by Ms. Izumiya, Mr. Totsuka and Ms. Takako Ito, patent attorneys of Yuasa and Hara.

2. The new Examination Guidelines for medicinal invention in general

The new Examination Guidelines include a compilation of criteria for judgments relating to medicinal inventions with regard to requirements for novelty, inventive step, written description and enablement etc., which are described in isolated parts of the existing Examination Guidelines. Also, the new Guidelines clarify special judgments and handlings of medicinal inventions under current Japanese patent practice. Further, the new Guidelines stipulate that medicinal inventions specified by mode of treatment such as dose interval or dosage, are also patentable (explained in detail in section 4 below).

In this section, a general explanation of the new Examination Guidelines relating to medicinal

inventions is presented.

(1) Novelty

The new Examination Guidelines stipulate that:

> *Novelty of the medicinal invention is judged from two view-points, namely, of one compound or one group of compounds having a specific property and of the medicinal use of such compound applied to a specific disease based on such property.*
>
> *(Excerpt form the new Guidelines)*

In other words, for the claimed medicinal invention to be novel, one compound or one group of compounds of the claimed medicinal invention should be distinguishable from that of the cited invention. Alternatively, when one compound or one group of compounds of the claimed and the cited inventions are the same, the medicinal use of the claimed and the cited inventions should be distinguishable.

(2) Inventive Step

Inventive step regarding medicinal inventions is judged in the same manner as the other invention in general. That is:

> *Whether or not a claimed invention involves an inventive step is determined based on whether the reasoning, that a person skilled in the art could have easily arrived at a claimed invention based on cited inventions, can be made by constantly considering what a person skilled in the art would do after precisely comprehending the state of the art in the field to which the present invention pertains at the time of the filing.*
>
> *(Excerpt from the Examination Guidelines Part II, Chapter 2, 2.)*

Further, the new Examination Guidelines present the following examples regarding judgment of inventive step.

> *(i) Even if the medicinal use of the claimed medicinal invention is different from the medicinal use of the cited invention, when relevance of the working mechanism between the both is taken out by the publicly known art or the common general knowledge at the time of the filing, ordinarily, the inventive step of the medicinal invention of the present patent application is denied, so long as there is not any other ground such as advantageous effect or the like which enables anticipated admission of the inventive step.*
>
> *(ii) A claimed medicinal invention, which is only a medicinal invention where one*

compound or a group of compounds of a cited invention which is for the same kind of or similar diseases of an animal other than a human being is simply converted to a medicine for the human being, is ordinarily recognized not to have the inventive step of the medicinal invention (NOTE: the rest of this paragraph is omitted).

The situation is the same with the conversion of a medicine for a human being to a medicine for an animal other than a human being.

(Excerpt from the new Guidelines)

(3) Written Description Requirement Regarding the Japanese Patent Law, Article 36(6)(i)

An invention stated in any claim shall not extend beyond the scope defined in the detailed description of the invention, under the provision of the Japanese Patent Law Article 36(6)(i). It is examined whether the claimed invention is substantially disclosed in the specification. That is, the original specification is required to include substantial descriptions supporting the whole scope of the claims.

Regarding the Japanese Patent Law, Article 36(6)(ii)

Further, claims should be stated in such manner that an invention for which a patent is sought can be clearly identified from a single claim, under the provision of the Japanese Patent Law Article 36(6)(ii).

It is possible to use various forms of expression in claims to define an invention for which a patent is sought. However, it should be noted that a definition of an invention described by various forms of expression is allowed only as long as the claimed invention can be clearly identified.

The new Examination Guidelines provide the following four examples as to how a medicinal invention can be described as an invention of a product in the claims:

Example 1: *A medicine for Disease Z containing an effective ingredient A.*

Example 2: *A medical composition for Disease Y containing an effective ingredient B.*

Example 3: *A medicine for Disease W containing effective ingredients combining an effective ingredient C and an effective ingredient D.*

Example 4: *A kit for treating Disease V consisting of an injection agent comprising an effective ingredient E, an oral agent comprising an effective ingredient F, and an agent comprising an auxiliary ingredient G.*

Further, if a medicinal invention is directed to a first use of a new effective ingredient X,

you may describe a claim as "a pharmaceutical composition comprising the compound X" without limiting specific medical use. Such claim description would not violate the written description requirement when the effective ingredient is novel.

(4) Enablement Requirement

The new Examination Guidelines stipulate that:

> *As a medical invention belongs to a technical field where it is generally difficult to infer how to make and use a product on the basis of its structure, normally one or* more representative embodiments or working examples which enable a person skilled in the art to carry out the invention are necessary.
>
> *(Excerpt from the new Guidelines)*

Under the current Japanese practice, it is important to include at least one working example of pharmacological data in the original specification. If such data is included, submission of supportive additional data during prosecution is generally acceptable. However, if there is no such data, submission of additional data is not acceptable. (Ref. Tokyo High Court Decision Case No. 1996 (gyo ke) 201, 30/10/1998, Tokyo High Court Decision Case No. 2001 (gyo ke) 345, 1/10/2002, Tokyo High Court Decision Case No. 2001 (gyo ke) 99, 22/12/2003)

The new examination guidelines stipulate that a working example of pharmacological data, should clearly describe all of the following:

(i) a specific compound which was tested;
(ii) a pharmacological test system which was applied;
(iii) a result(s) obtained by said pharmacological test system; and
(iv) a relationship between said pharmacological test system and the medicinal use of the claimed medicinal invention.

Further, in principle, the pharmacological data should be described with numerical data.

It should be noted that, basically, the JPO has actually already been following the practice described above, and this practice is now clarified in the new examination guidelines. Thus, based on the stipulation of the new examination guidelines, the JPO will even more strictly judge enablement requirement, i.e., whether the claimed medicinal invention is supported by such specific working example.

Further, pharmacological data can be obtained not only from an in vivo test such as a clinical test or an animal test, but also from an in vitro test.

3. Medicinal invention of a combination of more than two medicines.

The new Examination Guidelines clarify that a medicinal invention specified by a combination of more than two medicines is a patentable subject matter, since it is an invention of a "product".

(1) Novelty

Novelty of a medicinal invention specified by a combination of more than two medicines is judged in the same manner as a medicinal invention in general. That is, Novelty of the medicinal invention specified by a combination of more than two medicines is judged from two view points, i.e., a compound and a medicinal use.

(2) Inventive Step

The following Examples are intended to clarify concrete practice regarding judgment of inventive step relating to a medicinal invention of a combination of more than two medicines.

Case Example 1 (Unpatentable example: Combination of a component with another component having the same major action which is publicly known)

[Claim]

[Claim 1] A liquid antiflatulent, wherein the YY bacterium is contained at a ratio of 1 x 106 to 1 x 108 cells per 1 to 30g of dietary fiber.

[Outline of Detailed Description of the Invention]

In the invention, an antiflatulent which fortifies the intestine regulating function is formulated by combining the dietary fiber and the YY bacterium, both having an intestine regulating function. Furthermore, in the specification, ***a result of a pharmacological test*** *using the antiflatulent having this combination is shown. However, no specific description is made of the synergistic effect thereof.*

[Result of Prior Art Search]

It is publicly known that there is an intestine regulating function when 1 to 30g of the dietary fiber is taken or when 1 x 106 to 1 x 108 cells of the YY bacterium are taken. Further, it is also publicly known to combine said bacterium with dietary fiber, to maintain an activity of the bacterium having the intestine regulating function inside the body and to enhance the function.

[Outline of Reasons for Rejection]

Since the combined use of said bacterium with dietary fiber to maintain an activity of the

bacterium having the intestine regulating function inside the body and to enhance the function is publicly known, it would have been easy for those skilled in the art to conceive of the antiflatulent made by combining the YY bacteria having the intestine regulating function with the dietary fiber having the same function. Further, it can also be suitably achieved by those skilled in the art to formulate a liquid medicine as needed in view of easiness of taking or the like. Furthermore, the effect thereof cannot be considered to be especially remarkable.

[Measures for Reasons for Refusal]

Ordinarily, the above-described reasons for refusal cannot be withdrawn.

Even if the synergistic effects are not described, when an inference could be made that there exist the synergistic effects superior to the cited invention from the description or drawings by those skilled persons in the art, the synergistic effect insisted on or verified by applicant's exhibiting experimental results by written opinion are taken into consideration.

(Excerpt from the new Guidelines:underlines and emphases are added.)

Case Example 2 (Patentable Example; A medicine performing advantageous effect by combination of effective ingredients)

[Claims]

[Claim 1] An anticancer drug formulated by combining a compound A with a compound B.

[Claim 2] The anticancer drug according to Claim 1, wherein the anticancer drug is a compounding agent.

[Claim 3] The anticancer drug according to Claim 1, wherein the anticancer drug is a kit composed of an agent containing the compound A and an agent containing the compound B.

[Claim 4] The anticancer drug according to Claim 1, wherein the compound A is dosed through an administrating path selected from a group consisting of a vein path and a subcutaneous path, and the compound B is orally dosed, respectively with doses of 10 to 50mg/kg and 1 to 30mg/kg daily or three times in a week.

[Outline of Detailed Description of the Invention]

In the invention, a synergistic anticancer effect is found by combined use of the compound A and the compound B. Furthermore, indications are made that the use is possible in a state of a compounding agent in which both compound A and compound B are mixed or in a state of a kit in which both compound A and compound B are not mixed, and that a synergistic anticancer effect is performed by taking the compound A and the compound B simultaneously or with a certain interval. ***In the working example, a description is made of the result of the pharmacological test showing performance of the synergistic anticancer effect.***

[Result of Prior Art Search]

Although it is publicly known that the compound A and the compound B respectively have an anticancer effect, the anticancer agent using the compound A and the compound B in combination has not been described or suggested in any documents of the prior art. Furthermore, from the state of the art at the time of the patent application, it is not possible to predict the performance of the synergistic anticancer effect by combined use of both of the above-described compounds.

[Outline of Reasons for Rejection]

None.

[JPO's Comment]

When a synergistic anticancer effect exceeding the scope of the prediction made from the state of the art at the time of patent application by combined use of the compound A and the compound B is shown by the result of a pharmacological test or the like, there exists inventive step.

It should be noted that since the invention according to Claim 1 has novelty and inventive step in the combination of the compound A and the compound B, the invention which specifies a specific mode of the pertinent combination such as compounding agent, kit, or the like, like the inventions according to Claims 2 to 4 which quote Claim 1, it is judged that the inventions have novelty and inventive step in the same way as the invention according to Claim 1.

(Excerpt from the new Guidelines: underlines and emphases are added.)

These examples suggest that a mere combination of two or more medical ingredients itself does not constitute inventive step. For inventive step of the medicinal invention of a combination of more than two medicines to be acknowledged, the combination of the ingredients should be novel, and a remarkable effect such as synergistic effect should be performed by said combination. Thus, the JPO seems to judge inventive step of the medicinal invention of a combination of more than two medicines in a relatively strict manner.

Further, it should be noted that, in principle, it is necessary to describe at least one working example of pharmacological data by using the combination of medicines in the original specification, as the same as a medicinal invention of a single active ingredient. If such data is included in the original specification, an applicant can argue during prosecution that the medicinal invention has an advantageous effect (such as synergistic effect) based on such data, and, if necessary, by submitting further supportive data (see [Measures for Reasons for Refusal] in Case Example 1 above).

When an advantageous effect of the medicinal invention of a combination of more than two medicines is not sufficiently described in the original specification, the JPO seems to issue a rejection primarily based on lack of inventive step (not enablement requirement). As a consequence, under Japanese practice, the JPO seems to be slightly generous regarding submission of post-filing data. However, it should be noted that a description of remarkable effect, which serves as a basis for arguing inventive step of a medicinal invention, should somehow be included in an original specification.

4. Medicinal invention specified by a treatment mode.

The new Examination Guidelines stipulate that a medicinal invention specified by a treatment mode such as the dose interval and dosage, is a patentable subject matter, since it is an invention of a "product".

(1) Novelty

The new Examination Guidelines stipulate that novelty of a medicinal invention specified by a treatment mode is acknowledged when the treatment mode such as dosing interval, given dose, or the like of the claimed invention is different from that of a cited invention, and the medicinal use of the claimed invention is different from that of the cited invention in a manner described in the following (a) or (b):

(a) the target patient groups of the claimed and cited inventions are clearly distinguishable; or

(b) the treated area of the claimed and cited inventions are clearly distinguishable.

Further, the new Examination Guidelines further stipulate that novelty of a medicinal invention specified by a treatment mode can be acknowledged when said treatment mode is reflected in a dosage form or in a usage specified kit for treating, so that the dosage form or the kit can be distinguished from the cited invention.

(2) Inventive Step

The new Examination Guidelines clearly stipulate that "*optimization of the mode of the use of the medicine (dosing interval, given dose, or the like) is an exertion of ordinary creative ability of those skilled in the art*". In other words, a novel mode of treatment itself does not constitute inventive step. Inventive step is acknowledged when a remarkable effect such as synergistic effect is performed by the novel mode of treatment. As a consequence, the JPO seems to judge inventive step of the medicinal invention of a combination of more than two medicines in a relatively strict manner.

In principle, it is necessary to describe at least one working example of pharmacological data by using the treatment mode of the medicinal invention in the original specification as a medicinal invention of a single active ingredient. When an advantageous effect of the medicinal invention specified by a treatment mode is not sufficiently described in the original specification, the JPO seems to issue a rejection primarily based on lack of inventive step. As a consequence, under Japanese practice, the JPO seems to be slightly generous regarding submission of post-filing data. This is the same as the situation described above for a medicinal invention of a combination of more than two medicines. Thus, it should be noted that a description of remarkable effect should somehow be included in an original specification.

(3) Examples of the claim description

Further, the new Examination Guidelines provide several case examples regarding medicinal inventions specified by mode of treatment. Those examples provide us suggestions as to how we could draft claims for the medicinal invention specified by mode of treatment. The medicinal invention specified by mode of treatment can be described in the claims as, for example, (i) a medicine characterized by specific dosing interval and/or given dose; (ii) a medicine which specific dosing interval and/or given dose is reflected to the dosage form; and (iii) a kit for treatment which specific dosing interval and/or given dose is specified. The following Examples (i)-(iii) are excerpted from case examples of medicinal inventions specified by a treatment mode described in the new Examination Guidelines.

Example (i): Medicine characterized by specific dosing interval and/or given dose

Claim

[Claim 1] A pharmaceutical composition for treatment of hepatitis C comprising Compound A, wherein said composition is used to treat a patient having α -type genotype, and wherein said composition is characterized in administering in an amount of 5.0 mg/kg to 10.0 mg/kg at first time, and then administering in an amount of 0.3 mg/kg to 0.5 mg/kg per administration in alternate-day regimen.

Example (ii): Medicine for which specific dosing interval and/or given dose is reflected to the dosage form

Claims

[Claim 1] An immunopotentiating agent for oral administration characterized in being formulated to contain 550 mg to 650 mg of a compound Z or its pharmacologically admissive

salts per single dosage unit.

[Claim 2] An immunopotentiating agent for oral administration described in Claim 1, wherein said formulated immunopotentiating agent for oral administration is in a form of tablet.

Example (iii): A kit for treatment which specific dosing interval and/or given dose is specified

Claim

[Claim 1] A kit for 2-stage contraception applied for oral administration, comprising one-day dosage unit, wrapped in one wrapping unit spatially separated, containing two kinds of effective ingredients to be dosed orally one after another, each of which is spatially separated in the wrapping unit and stored so as to be able to be individually taken out, and the first effective ingredient being a tablet containing 0.01 to 0.04 mg of only the compound A as a one-day dose unit, and the second effective ingredient being a tablet containing 0.50 to 1.00 mg of the compound B as a one-day dose unit, total number of one-day dose units being equal to the total number of days of the required menstrual cycle, and the tablets containing the first effective ingredient being 4 to 6 day dose units and the tablets containing the second effective ingredient being 21 days dose units.

(NOTE: This claim is excerpted from an example of a case which is unpatentable due to lack of inventive step.)

(Excerpt from the new Guidelines)

5. Conclusion

The newly established "Examination Guidelines for Medicinal Invention" are briefly explained above. In the new Examination Guidelines, requirements for novelty, inventive step, written description and enablement etc., of the medical invention for which special judgments and handlings are necessary, are made clear.

Further, as for medicinal inventions which are to be specified by a combination of two or more medicine or a treatment mode such as the dose interval and dosage, it is made clear that such inventions are patentable subject matter when described as an invention of a "product". This will enable us to claim a pharmaceutical composition characterized by modes of treatment. However, the JPO stands on a point that inventive step of a medicinal invention characterized by a mode of treatment lies in a remarkable effect actualized by the novel mode of treatment. Thus, it should be noted that a remarkable effect should be described or disclosed in an original specification.

Shinobu Fukusho (Ms., Ph.D.);
Patent Attorney of the Patent Division

"Recognition Procedure" under the Customs Tariff Law

1. What is the "recognition procedure"?

Article 21, paragraph 1 of the Customs Tariff Law provides that "any goods specified in any of the following sub-paragraphs shall not be imported." Sub-paragraph 5 defines such goods as "articles infringing upon rights in patents, utility-models, designs, trademarks…." Also, article 21, paragraph 2 provides that "the Director-General of Customs shall be authorized to confiscate and destroy goods provided for in sub-paragraph 5 of the preceding paragraph which were to be imported, or to order any importer to reship such goods."

A patent right holder can file with the Director-General of Customs for the recognition procedure to be applied, including the requisite evidence of the fact of infringement (article 21-2, paragraph 1 of the Customs Tariff Law). The term "recognition procedure" is defined as a procedure in which import goods suspected of infringing intellectual property ("IP") rights are deemed to be goods infringing IP rights.

2. Outline of the recognition procedure

(for details, see the Japan Customs website)

a. When a customs officer conducts an inspection and finds import goods suspected of infringing patent rights, the recognition procedure begins (except for cases of smuggling).
b. If the recognition procedure is begun, the customs officer delivers a "Notice of Initiation of Recognition Procedure" to the patent right holder and to the importer.
c. The patent right holder and the importer submit a written opinion and evidence concerning the subject goods to the customs officer within 10 business days from the day after of the date of "Notice of Initiation Recognition Procedure."
d. The patent right holder's opinion and evidence are disclosed to the importer to the extent that it can be disclosed. By the same token the importer's opinion etc. is disclosed to the patent right holder. The customs officer asks the parties to submit a rebuttal. The customs officer recognizes whether the subject goods correspond to patent infringing goods based on submitted the opinions etc..
e. The customs officer delivers to the parties a "Notice of Recognition" regarding the result of the recognition.

3. Point of the recognition procedure

Whether an import injunction based on patent rights is granted depends on whether the customs

officer can judge infringement at first sight, comparing the claim of patent rights to the import goods. In other words, the judgment whether the import goods should be deemed goods infringing patent is transferred to the customs officer's discretion.

For example, if a patent right holder files with the Director-General of Customs for the recognition procedure to be applied based on a patent right related to a semiconductor circuit, it would be very difficult for a customs officer to ascertain the presence of infringement by visual inspection. Thus, it is unlikely that the customs officer will decide that the import goods are infringing goods. In contrast, a customs officer can decide that import goods are infringing goods by visual inspection, for example, of constitution of a DVD player's inner parts, and it is highly likely that the import injunction would recognized.

Thus, a most important element of the recognition procedure is to provide the information to distinguish patent infringing goods easily because the discovery of such goods is the role of each customs officer.

4. Result of import injunction in 2004

The number of import injunctions regarding IP infringing goods was 9,143 cased in 2004 (Ministry of Finance). Of that number, patent infringing goods constituted only 80 cases (Trademark infringement goods reached 8,922 cases.). The numbers indicate that it is difficult that for a customs officer to judge whether import goods correspond to patent infringing goods.

Koji Sakuma (Mr.);
Attorney-at-law of the Law Division

Nichia Corporation "Blue LED" Case: Settlement between Professor Nakamura and Nichia at the Tokyo High Court regarding reasonable compensation for an employee's invention

1. Overview

With this report, we follow up on our previous article on the "Blue LED" case, which centered on the notion of reasonable compensation for an employee's invention (*See* YUASA and HARA INTELLECTUAL PROPERTY NEWS Vol.14).

On August 23, 2001, Mr. Shuji Nakamura, now a professor at the University of California, Santa

Barbara, filed an action in Tokyo District Court against his former employer, Nichia Corporation, seeking JP¥ 20 billion (about US$185,718,272.00 as of June 6, 2005) as reasonable compensation for his invention regarding the blue light-emitting Diode (LED).
On January 30, 2004, the court found that "reasonable compensation" under Article 35, Paragraph 3 of the Patent Law was JP¥ 60,436,060,000 (about US$561,148,288.00 as of June 6, 2005). As the amount sought by the plaintiff was JP¥ 20 billion, the court held that Nichia must pay this latter amount to the plaintiff. Both Professor Nakamura and Nichia immediately appealed to the Tokyo High Court.

On January 11, 2005, Professor Nakamura and Nichia reached a settlement mediated by the Court of Appeal of the 6th Civil Division of the Tokyo High Court.

2. <u>Terms of the settlement</u>

The terms of the settlement, which Nichia has released on its web site, are as follows:

(1) Professor Nakamura shall confirm that he has assigned to Nichia all rights to receive patents (including Japanese patents, Japanese utility models and any corresponding rights in foreign countries) regarding all of his employee's inventions during his employment at Nichia.
(2) Nichia shall confirm that it is under a duty to pay JP¥608,570,000 (about US$5,651,128.00 as of June 6, 2005), as reasonable compensation for his invention in exchange for transferring the invention to Nichia, and JP¥235,340,000 as damages for delay in payment.
(3) Nichia shall pay the JP¥843,910,000 (about US$7,752,902 as of June 6, 2005) provided in Article (2) to Professor Nakamura by remittance to a designated bank account by the end of January 2005.
(4) Professor Nakamura shall consent to Nichia's motion for canceling compulsory execution, and both Nichia and Professor Nakamura shall not appeal the court's ruling on the motion.
(5) Professor Nakamura shall waive any other claim in this case.
(6) Both Professor Nakamura and Nichia shall confirm that this case and any other dispute regarding an employee's invention of Professor Nakamura are settled by this settlement.
(7) Both Professor Nakamura and Nichia shall confirm that there are no debts or credits between them except for this settlement with respect to this case.
(8) Both Professor Nakamura and Nichia shall bear their own costs of the lawsuits in the proceedings at both the District Court and the High Court.

3. Differences between the Judgment of the Tokyo District Court and the Settlement at Tokyo High Court

	Tokyo District Court	Tokyo High Court
Rights at issue	One registered patent (Reg. No. 2,628,404)	All inventions during his employment, including 191 registered patents, 4 registered utility models, 112 pending patent applications, and their corresponding rights in foreign countries and know-how
Profits of exclusivity = (a) Total sales of products × (b) Excess sales rate × (c) Royalty rate Reasonable compensation = (d) Profits of exclusivity × (e) Percentage of contribution of employee to the invention		
(a) Nichia's total sales of products	JP¥1,208,601,270, (from 1994 to 2010 when the rights at issue will expire) *The Court ignored blanket cross license	(i) Before entering blanket cross license (from 1994 to 2002): JP¥201,973,160,000 (ii) After entering blanket cross license (from 2003 to 2012, when some of the important patents included in the rights at issue will expire): JP¥5,011,830,000 * As an adjustment, the Court multiplied by 70% Nichia's sales amount after entering blanket cross license instead of multiplying royalty rate, because the Court cannot predict Nichia's sales amount and royalty rate it cannot calculate precisely the profits of exclusivity after the blanket cross license.
(b) Excess sales rate due to exclusivity	50%	50%
(c) Royalty rate for the rights at issue	20%	10% for the initial 3 years 7% thereafter and before entering blanket cross license * The Court reduced the rate by 3% to account for advances in the technical field to which the rights at issue belong. * No royalty rate after entering blanket cross license (*See* (a)(ii))
(d) Profits of exclusivity	JP¥120,860,120,000	(a)(i) JP¥7,159,750,000 (a)(ii) JP¥5,011,830,000 Total: JP¥12,171,580,000
(e) Percentage of contribution	Professor Nakamura: 50% Nichia: 50% Factors the court took into account:	Professor Nakamura: 5% Nichia: 95% *Factors the court took into account:

	* Professor Nakamura almost solely developed the invention based on his own idea without technological backup and human resources	--Article 35 of the Patent Law was provided not only to enhance employees' motivation but also to assist business enterprise to overcome obstacles and achieve development --Court precedents including the *Hitachi* case, (*See* YUASA and HARA INTELLECTUAL PROPERTY NEWS Vol.14) --Fact that this is an isolated case because the reasonable compensation is an extremely large amount
Amount of reasonable compensation	JP¥60,430,060,000 (US$561,148,288.00 as of June 6, 2005)	JP¥608,570,000 (US$5,651,128.00 as of June 6, 2005, 2005)

4. Comments from the court and parties

(1) Tokyo High Court

After the parties reached the settlement, the Tokyo High Court opened on its web site a document titled "The Court's thinking on the settlement." It is quite rare for the court to announce to the public its views on a settlement. In the document, the court explained (1) the reasons why it advised settling this case, (2) the basic concept of Article 35 of the Patent Law, (3) the amount of reasonable compensation for all of Professor Nakamura's inventions during the term of his employment and (4) a chart to calculate reasonable compensation to him.

Although the ideas expressed in "The Court's thinking on the settlement" do not constitute legal precedent, they will serve as a beacon for the future. In particular, the Court mentioned that the purpose of Article 35 of the Patent Law was not only to enhance employees' motivation to invent but also to allow business enterprise to overcome obstacles and develop in difficult economic times and in international competition. In addition, the Court mentioned that when reasonable compensation is an extremely huge amount, the inventor's percentage contribution should be reduced.

The court also mentioned that an employee's reasonable compensation should be distinguished from the ordinary risks that a business enterprise runs in order to be successful in the market. While these ordinary risks cannot be easily reduced, the risks associated with having to pay an enormous reasonable compensation can and should be reduced.

The document should serve as a useful reference in future for companies, employee inventors and attorneys in handling cases of this sort.

(2) Professor Nakamura

"Totally dissatisfied, absolutely furious," Professor Nakamura said at the press conference after entering the settlement. He also showed deep distrust of the Tokyo High Court and said, "I cannot understand how the Court calculated 60.4 billion Japanese yen. The Court never read my briefs."

On the other hand, he explained the reason why he accepted the settlement, noting, "My attorneys said that there is no possibility that neither the Tokyo High Court or the Supreme Court will grant a higher amount of reasonable compensation than that of the settlement." Lastly he said, "The judicial system in Japan is rotten. I am outraged. That's all I have to say."

(3) Attorneys for Professor Nakamura

After the settlement had been entered into, Hidetoshi Masunaga, attorney for Professor Nakamura, said, "The amount of reasonable compensation in the settlement is lower than that found by the Tokyo District Court, however, Professor Nakamura won this case as a matter of practice. Because this kind of money didn't exist four years ago, so that this is a great incentive for Japanese corporate engineers. Japanese society is starting to change dramatically". On his law firm's web site, he also announced the outcome of the case and explained in detail the reasons why they accepted the settlement.

(4) Nichia

On its web site, Nichia noted its belief that the Court will basically understand its claims, particularly that the invention regarding the blue LED was brought into existence not by one person, but by the efforts and innovations of many people.

5. Japan for engineers

Article 35 of the Japanese Patent Law has been amended, the new version having come into effect on April 1, 2005 (*See* YUASA and HARA INTELLECTUAL PROPERTY NEWS Vol.15).
Because of the amendment and current court precedents, including this case, a large number of companies have revised their internal rules regarding employee's inventions to the benefit of employees. This trend is worth watching.

Professor Nakamura advised engineers in Japan, saying, "I don't think engineers will want to work in Japan anymore. I plan to recommend to people in science and engineering to come to the United States where their abilities are reflected in their income."
However, taking into account not only compensation for inventions, but also stable employment relationships, studying circumstance, revised new Patent Law and changing the trend regarding employee's invention, I believe that Japan is still an attractive country for engineers.

Norimasa Shimoda (Mr.);
Attorney-at-law of Law Division