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Amendment of the Japanese Patent Law and other Industrial Property Laws in 2003

Introduction

The bill for the amendment of the Japanese Patent Law and other Industrial Property Laws was passed by the Diet in May 23, 2003. The main items of the amendment are as follow:

[1] Amendment of patent-related fee system

1. Amendments of Official fees, including the patent application fee, the fee for requesting examination, and the annual fee for a granted patent
2. Introduction of a system of refund of the fee for requesting examination
3. Extended coverage by schemes of reduction or deferment with regard to the fee for requesting examination, and so on

[2] Reform of the appeal and suit systems for achieving prompt and precise settlement of disputes

1. Introduction of a new invalidation appeal system
2. Expansion of opportunity for attack and defense in an invalidation appeal
3. Introduction of a system for requesting opinions and presenting opinions
4. Adjustment of the procedural relationship between a correction appeal and a suit for canceling a decision in an invalidation appeal

[3] Harmonization of the Japanese patent system with the global standard

1. Adjustment of the requirement of unity of invention to bring it into conformity with the PCT standard
2. Removal of regulations regarding the designation and selection of countries for PCT applications

[1] Amendment of patent-related fee system

The purpose of this amendment is to adjust the cost of obtaining a patent right, so as to promote rapid and fair protection of intellectual property rights. Specifically, the following changes are to be put into effect.

- (1) Amendments of Official fees, including the patent application fee, the fee for requesting examination, and the annual fee for a granted patent.
- (2) Introduction of a system of refund of the fee for requesting examination.
- (3) Extended coverage by schemes of reduction or deferment with regard to the fee for requesting examination, and so on.

The Japanese Patent Office announces that the fees that are to be newly introduced by these amendments will be subject to revision within five years after their introduction.

1. Amendment of the patent application fee, the fee for request for examination, and the annual fee for patent

Recently, an increasingly large number of requests for examination have been filed for patent applications of poor patentability. The effect of this trend has been to increase the workload of the patent office, and thus lengthen the time that applicants in general must wait before learning of the outcome of examination. To suppress this trend, it has been decided to raise the fee for requesting examination, with the intention of suppressing the number of patent applications entering the examination stage. It is hoped that as a result the problem of delays in examination can be alleviated.

Concurrent with raising the fee for requesting examination, the patent application fee has been lowered, and so has the annual fee for maintaining a patent. The result of the changes made to fees is that the overall cost per patent will remain equivalent to that under the existing law.

(1) Patent application fee

The fee for filing a patent application is to be reduced from the

existing rate of ¥ 21,000 to a new rate of ¥ 16,000. Further, the fee for filing an application in a foreign language will be reduced from the existing rate of ¥ 35,000 to a new rate of ¥ 26,000. These new fees will be applicable to patent applications filed on and after **April 1, 2004**.

(2) Fee for request for examination

The existing fee for requesting examination is determined as follows:

¥ 84,300 + ¥ 2,000 × number of claims.

This fee structure is to be amended as follows:

¥ 168,600 + ¥ 4,000 × number of claims.

This new rate is to be applied to patent applications filed on or after **April 1, 2004**.

(3) Annual fee for patent

The annual fee for patent is to be revised as shown in the table below. The revised annual fee for patent is to be applied to a patent application for which a request for examination is submitted on or after **April 1, 2004**, irrespective of filing date.

Accordingly, where an application was filed on or after April 1, 2001, and a request for examination is to be submitted, it is recommended that the applicant carefully consider the date of request for examination. Not only will requests for examination submitted on or after **April 1, 2004** be subject to the existing (lower) fee for request for examination, but also the revised (lower) annual fee for patent will apply.

Official fee of Annuity fee

1-3 years	Annually: ¥ 2,600 plus ¥ 200 per claim
4-6 years	Annually: ¥ 8,100 plus ¥ 600 per claim
7-9 years	Annually: ¥ 24,300 plus ¥ 1,900 per claim
10-25 years	Annually: ¥ 81,200 plus ¥ 6,400 per claim

(4) Notes regarding divisional applications and converted applications

For a patent application (a divisional application or a converted application) that is deemed to have a filing date identical with that of the original application, in accordance with the provisions of Article 44, Section 2 or Article 46, Section 5 of the Patent Law, the applicable fees may be determined based on the actual filing date of the divisional application or the converted application.

2. Introduction of system of refund of the fee for request for examination

This system will allow an applicant to obtain a refund of one half of the fee for requesting examination in a case where the subject application is abandoned or withdrawn before examination has begun. This is a new system under the Japanese Patent Law. Sections 9 and 10 of Article 195 of the Japanese Patent Law pre-

scribe the following provisions:

Article 195

9. After a request for examination has been submitted for a patent application, if the subject application is abandoned or withdrawn before any of an order, a notification or a service of a copy of an examiner's decision, as described below, has been made, an amount specified under the ordinance of the cabinet shall be refunded, upon request, to a person who has paid a fee for request for examination in accordance with the provision of Article 195, Subsection (2).

- 1) Order in accordance with provision of Article 39, Subsection (7);
- 2) Notification in accordance with provision of Article 48-7;
- 3) Notification in accordance with provision of Article 50; or
- 4) Service of a copy of the examiner's decision in accordance with provisions of Article 52, Subsection (2)

10. The refund of a portion of the fee in accordance with the preceding subsection shall not be requested later than six months after the date of abandonment or withdrawal of the subject patent application.

The above article will now be explained. If a patent application is abandoned or withdrawn before: (1) a directive is issued ordering all applicants to reach agreement, in a case where two or more applications relating to the same invention were filed on the same day, (Article 39, Subsection 7 of the Patent Law), (2) a notification of failure to satisfy the requirement for disclosure of information on prior art documents is issued (Article 48-7), (3) an office action rejecting a patent application is issued (Article 50), or (4) a decision of allowance or a decision of refusal is issued (Article 52, Subsection 2), then the applicant shall be entitled to request a refund of a portion of the fee.

It is to be noted that only those applicants who have paid the full fee for requesting examination are entitled to request a refund.

Refund of the fee for requesting examination may be requested on or after April 1, 2004. Specifically, where a patent application awaiting examination is abandoned or withdrawn on or after October 1, 2003, the applicant will be entitled to request a refund of the fee for requesting examination on or after **April 1, 2004**.

3. Extended coverage by schemes of reduction, exemption or deferment with regard to the fee for request for examination and so on

Conventionally, under the Patent Law, fees have been reduced, or payment of fees has been deferred for persons or corporations with limited financial resources, and further, fees have been reduced for small to medium-sized enterprises involved in

research and development. Under the current revision of the Patent Law, this coverage has been extended. Below, we provide an outline of the revision.

(1) Extended coverage by the reduction and deferment scheme for a corporation having limited financial resources

According to the amendment, the range covered by the term “a corporation having limited financial resources” will be extended. Specifically, a corporation-tax free enterprise with a capital fund not greater than 300 million yen and which has been established for less than 10 years, will be entitled to a reduction of one half of the fee for requesting examination, and to deferment of payment of the annual fee for patent (1-3 years).

(2) Reduction and deferment scheme for a joint application

Under the existing Patent Law, even a small or medium-sized enterprise to which the above reduction and deferment scheme can be applied (eligible small or medium-sized enterprises), shall not be entitled to a reduction in the fee and so on unless the subject application is a sole application. However, where a joint application is submitted by an eligible small or medium-sized enterprise, with some other entity (for example, a university, large enterprise), this amendment enables the eligible small or medium-sized enterprise to be covered by the reduction and deferment scheme, to an extent proportionate to its share of a patent right or a right to obtain a patent.

(3) Others

Independent administrative institutions handling tasks relating to experiments and research, as well as experimental and research institutions of local authorities shall also be covered by the reduction schemes relating to payment of the annual fee for patent and the fee for request for examination (the Industrial Technical Capability Enforcing Law (Sangyou Gijutsu-ryoku Kyouka Hou)).

The revisions relating to the reduction or deferment schemes, with regard to payment of fee for request for examination and so on, shall be applicable to those patent applications filed on or after **April 1, 2004**.

Takami Ito (Ms.);
Patent Attorney of the Patent Division

[2] Reform of the appeal and suit systems for achieving prompt and precise settlement of disputes

Under the current system in Japan, procedures for settling patent validity disputes are available as follow:

- i) filing an opposition against a patent;
- ii) filing an appeal for invalidation of a patent (invalidation appeal);
- iii) filing an appeal for correction of a patent (correction appeal); and
- iv) filing a suit for canceling a decision made in an invalidation appeal.

However, the procedural system outlined above is perceived to be problematic. Particularly, it has been pointed out that the procedures involved in the system are excessively time-consuming and burdensome for the parties involved. In view of such problems, it is an objective of the present amendment to facilitate prompt and fair settlement of disputes arising with regard to patents and other industrial properties. This objective is to be achieved by reviewing and rationalizing the current systems in place.

1. Introduction of a new invalidation appeal system

Under the current Japanese Patent Law, two systems exist for disputing validity of a patent, namely, filing an opposition against a patent, and filing an appeal for invalidation of a patent. However, the coexistence of these two systems has proved to be less than satisfactory in that, for example, long delays may occur in reaching final settlement of a dispute in a case that both an opposition and an invalidation appeal are filed against the same patent; a situation that frequently occurs. In resolving the problems inherent to the present systems for disputing validity of a patent, it has been desired to establish a system that will meet the fundamental need for prompt examination and settlement of patent validity disputes by way of a single unified procedure; and which will also ensure that fair and credible decisions are made. Accordingly, by the present amendment of the law, the opposition system has been abandoned, and a new, unified invalidation appeal system has been put into place. One important feature of the new invalidation appeal system is that any third party is now entitled to dispute validity of a patent right. In the following section, I will provide an outline of the new invalidation appeal system.

(1) In the new invalidation appeal system, any third party can file a demand for appeal. However, if the reasons for invalidation relate to those of attribution of patent right, such as breach of a requirement of a joint application or a misappropriated application, a specific interest shall be required (Article 123, par. 2). In this respect, the new invalidation appeal system differs from the old (present) system in that in the old system a demonstrable interest is a mandatory regardless of the reasons for invalidation.

(2) Other points such as timing of a demand, and reasons for invalidation are identical to those under the old invalidation appeal system.

- An appeal may be demanded at any time.
- Proceedings shall be carried out between the demandant and the defendant (patentee) (inter-parties structure). If necessary, the JPO may proceed with investigation *ex officio*.
- Both the demandant and the defendant may file an appeal with the Tokyo High Court for canceling a decision issued by the JPO.

(3) The Utility Model Law and the Design Law have also been similarly revised, and any third party is now entitled to file a new invalidation appeal.

2. Expansion of opportunity for attack and defense in an invalidation appeal

After the amendment of the Japanese Patent Law in 1998, an allowable amendment of reasons for invalidation after demanding an appeal was greatly restricted. The objective of the amendment was to shorten a time required for an appeal examination to be conducted. However, in practice, the effect of the amendment has been that multiple invalidation appeals are repeatedly demanded against a single patent. In contrast, as a result of the amendment of the Japanese Patent Law in 1993, for a patentee, opportunities for correcting claims and a specification of a patent in an appeal procedure have been restricted. Specifically, correction can be made only during a period in which a first written reply to the written demand of appeal can be submitted, and within a period when a reply to an Official Action, if any is issued, notifying reasons for invalidation found by the appeal examiners *ex officio*.

Under the new invalidation appeal system, an opportunity for attack afforded to a demandant, and that for defense to a defendant has been expanded. The objective of this change is to enable appropriate appeal examination to be conducted, and early and conclusive settlement of disputes to be reached

(1) Requirements for describing “reasons for invalidation” in a written demand of appeal are explicitly stipulated under the Japanese Patent Law. Specifically, the legal requirements for “reasons for invalidation” applicable in filing a demand for appeal after amendment are as follow:

Article 131 par. 2

The reasons for demanding an invalidation appeal “must be such that they specifically point out the facts that provide grounds for invalidating the patent, and which describe the relation with evidence of each of the facts that need to be proved.”

(2) Chief appeal examiner may allow the demandant to amend reasons for invalidation under certain conditions. However, to make an amendment, all four requirements shall be met (Article 131^{bis}), as follow:

- i) an amendment should not cause undue delay in appeal examination;

ii) there should be a rational explanation as to why a demandant was unable to describe newly introduced reasons for invalidation of amendment in an original demand for appeal at the time of filing a demand for appeal;

iii) a patentee agrees with filing of the amendment; and

iv) an amendment of reasons for invalidation is not filed before transmittal of a copy of a demand of invalidation appeal to a patentee.

If a patentee files a demand for correction, and the correction gives rise to a need for the demandant to amend reasons for invalidation that have been filed, the requirements of ii) and iii) are met.

(3) Opportunity for a patentee to re-submit a written reply and to demand correction is explicitly provided for under the revised Japanese Patent Law. Specifically, if an amendment of reasons for invalidation is submitted by a demandant, a copy is automatically transmitted to the patentee. The patentee is then given a further opportunity to submit a written reply, and also a further demand for correction (Article 134, par. 2, and Article 134^{bis})

3. Introduction of a system for requesting opinions and presenting opinions

A new system has been introduced such that the court may request opinions from the JPO, and such that the JPO may present opinions in a suit filed for canceling a decision in an invalidation appeal. This new system provides for involvement of the JPO in a suit, and also sharing of information between the JPO and the court.

System for requesting opinions and presenting opinions

Article 180^{bis}

(1) The court may, if a suit for canceling a decision in appeal for patent invalidation has been instituted, request the Commissioner of the Patent Office to give opinions on, for example, the application of laws concerning the case at issue.

(2) The Commissioner of the Patent Office may, if a suit for canceling a decision in appeal for patent invalidation has been instituted, put forward opinions to the Court on, for example, the application of laws concerning the case at issue.

The Utility Model Law and the Design Law have also been revised to introduce a system for requesting opinions and presenting opinions.

4. Adjustment of the relationship in the procedures for filing a correction appeal and for filing a suit for canceling a decision in an invalidation appeal

Under the current law, opportunities for filing a demand for correction during procedures of an invalidation appeal are highly limited. Due in part to this situation, patentees often file a demand of appeal for correction of a patent after a decision in an invalidation appeal has been issued; and then a suit for canceling

a decision made in an invalidation appeal is filed. Under the current practice, after an appeal decision accepting correction of a patent is confirmed, the court automatically revokes the original decision made in the invalidation appeal, and remands the case to the JPO. This unsatisfactory situation, whereby cases are passed between the JPO and the Tokyo High Court, is referred to in Japanese as “*CATCH-BALL GENSHOU*” (“playing catch” phenomenon); and results unfruitful suit proceedings, ineffective appeal examinations, and time-consuming examination.

By this amendment of the law, a time for demanding a correction appeal after issuance of a decision in an invalidation appeal is limited. Further, a new system is introduced which enables the court to revoke an original appeal decision, and to make a decision to remand the case to the JPO even before any correction is accepted. The result of this amendment will be to enable early settlement of patent right disputes. Below, I provide information in detail on the amendment.

(1) Limitation of time for demanding a correction appeal after issuance of a decision in an invalidation appeal (Article 126, par.2)

A demand for an appeal for correction of a patent may be accepted only **within 90 days** from the date of filing a suit for canceling a decision in an invalidation appeal.

(2) Introduction of a new decision system for revocation of an original appeal decision by the court (Article 181, par.2)

Requirements for decision of revocation

- i) The patentee has filed or is preparing to file a demand of correction appeal with the JPO after filing a suit for canceling a decision in an invalidation appeal.
- ii) It is recognized by the court that it is appropriate for the case to be re-examined in an invalidation appeal at the JPO.
- iii) The court should hear opinions from both parties on remand of the case.

Effects of decision of revocation

The court may revoke an original appeal decision, and make a decision to remand the case to the JPO. Such a decision is to be made at the discretion of the court, without any substantial examination and can be made **before an appeal decision accepting correction of the patent has been confirmed.**

(3) Further opportunity for correction of a patent in a re-appeal for invalidation after remand, as well as adjustment between correction appeal and re-appeal for invalidation (Article 134^{ter})

The patentee is given a further opportunity to submit a demand for correction in a re-appeal for invalidation after a case is remanded to the JPO. If a correction appeal had already been filed with the JPO before remand, procedures for correction in the correction appeal and in the re-appeal for invalidation are combined for further examination in the re-appeal for invalidation.

5. Others

The effective date for the new regulations regarding the new appeal and suit systems is **January 1, 2004**. In invalidation appeals and correction appeals, the new law is applied if these appeals are filed after the effective date. This means that no opposition can be submitted on or after January 1, 2004. At court, new regulations regarding suits for canceling decisions in invalidation appeals are applied if the original appeals are filed with JPO after the effective date.

[3] Harmonization of the Japanese patent system with the global standard

1. Adjustment of the requirement of unity of the invention with the PCT standard

It has been pointed out that “the requirement for unity of invention” which can be filed in a single application in Japan does not concur with that of other countries, or that employed under the Patent Corporation Treaty (PCT). Therefore, Article 37 of the Japanese Patent Law regulating the requirement for unity of invention has been revised as follows:

Article 37

Two or more inventions can be filed in a single application if they correspond to a group of inventions which, by having a certain technical relationship, satisfy the requirement of unity of invention.

The objective of the amendment is to bring the Japanese standard into accord with the requirement for unity of invention with that applied for PCT applications. At this stage, we can report that the JPO is in the process of reviewing and revising the relevant guidelines. We anticipate that a revised version of the guidelines will be published either in the summer or autumn of 2003.

2. Removal of regulations regarding the designation and selection of countries for PCT applications

By the amendment of PCT rules, which will become effective from January 2004, a system will be introduced such that it will be presumed that all PCT contracting states are automatically designated in a PCT application. Taking into account this amendment of the PCT rules, the regulations in Japan regarding the designation and selection of countries for PCT applications have been removed.

These amendments regarding harmonization of the Japanese patent system with the global standard will come into effect from **January 1, 2004.**

Reiko Izumiya (Ms.);
Patent Attorney of the Patent Division

Recent Judgment of Supreme Court regarding Employee's Invention under Article 35 of the Patent Law

Case: No. 13 (Ju) 1256

Monetary Compensation Claim

Date: April 22, 2003

Judgment: by the Third Petty Bench

Gist:

1. An employee, who assigned to his employer his right of receiving a patent for an invention made fore hire, may claim a deficiency from the employer if the amount of consideration provided in office regulations or other rules is less than the reasonable amount of consideration under Article 35, paragraphs 3 and 4 of the Patent Law.
2. The period of extinctive prescription of the right to receive payment of reasonable consideration under the provision of Article 35, paragraph 3 begins from the date of payment if office regulations or other rules previously set by the employer include a provision related to the date of payment of consideration.

Contents:

Case: Monetary Compensation Claim (Supreme Court No. 13 (Ju) 1256; dismissed by judgment of the Third Petty Bench dated April 22, 2003)

Original Instance: Tokyo High Court (No. 11 [Ne] 3208)

Text

1. This appeal is dismissed.
2. Section 1 of the text of the judgment of the initial court shall be modified as follows:
"1. the defendant shall pay to the plaintiff ¥ 2,289,000 and interest thereon at the rate of 5% per year from March 23, 1995 to the date of completion of payment. Other claims by the plaintiff are dismissed".
3. The appellant shall bear the cost of appeal.

Reasons

Part I. Outline of Case

1. This is a case in which the appellee, who was an employee of the appellant, claimed payment of reasonable consideration from the appellant under Article 35, paragraph 3 of the Patent Law for the assignment to the appellant of his right of receiving a patent for an invention made fore hire.
2. The outline of the factual circumstances legally confirmed in the original instance is as follows:
 - (1) The appellant is a company engaged in manufacture, sale, etc., of optical instruments. The appellee was employed by the appellant in May 1969 and was in the R&D Division of the appellant from 1973 to 1978 and engaged in the research and development of videodisc devices. The appellee quit the company in November 1994.
 - (2) The appellee made an invention called "pickup device" in 1977, which is described in section 3 of the List of Patent attached as a Schedule to the judgment of the initial court (hereinafter "Subject Invention"). The Subject

Invention belongs to the scope of business of the appellant and also job duties of the appellee and constitutes an invention made for hire under Article 35, paragraph 1 of the Patent Law.

- (3) The appellant set the "Rules for Handling Inventions and Conceptions" for inventions made for hire by the employees (hereinafter "Appellant's Rules"). The Appellant's Rules provide, among others, that an employee shall assign to the employer his right of receiving a patent for an invention made fore hire, that the appellant shall give to the employee, who made an invention made fore hire, a reward such as a reward for receiving income from industrial property rights, and that the appellant shall give to the employee a one-time reward not exceeding ¥ 1,000,000 for receiving income from industrial property rights for 2 years from the first date of receiving income from industrial property rights if the appellant continuously receives from a third party any income from industrial property rights for the employee's invention made for hire.
 - (4) The appellant succeeded to the appellee's the right of receiving a patent for the Subject Invention based on the Appellant's Rules, and applied for a patent therefor and received a patent. The appellant concluded license agreements with manufacturers of pickup devices in and after October 1990 for this patent and many other patent and utility model rights related to the pickup device, and thereafter continuously received royalties.
 - (5) In relation to the assignment of the right of receiving a patent for the Subject Invention to the appellant, the appellee received from the appellant ¥ 3,000 as compensation for patent application on January 5, 1978, ¥ 8,000 as compensation for registration on March 14, 1988, and ¥ 200,000 as a reward for receiving income from industrial property rights based on the Appellant's Rules.
3. In the above factual circumstances, the initial court judged that the appellee's claim should be accepted, that the appellee should receive payment of ¥ 2,289,000 (¥ 2,500,000, which was the amount recognized as reasonable consideration in this case, minus the amount of a reward for receiving income from industrial property rights and other amounts already received by the appellee), and further judged that:
 - (1) if the amount of consideration for an invention made for hire calculated according to the office regulations or other rules set by the employer is less than the reasonable amount of consideration under Article 35, paragraphs 3 and 4 of the Patent Law, the employee shall not be restricted by the amount calculated by the employer according to such rules but may claim reasonable consideration under said paragraphs; and
 - (2) the income from industrial property rights forming the basis for calculation of the reasonable consideration had not been clearly known until October 1, 1992 when the reward for receiving income from industrial property rights was given to the appellee, and the amount of reward receivable by the appellee was uncertain. Thus, the circumstances did not allow the appellee to exercise his right of receiving payment of reasonable consideration. Therefore, the period of extinctive prescription did not start until that date, and the extinctive prescription of the appellee's above right was not complete as of March 3, 1995 when the appellee initiated the subject proceedings.

Part II. Concerning Reason 1 for Petition for Acceptance of Appeal presented by the Appellant's Attorneys, Masashige Ohba, Osamu Suzuki and Shigeru Ohira

1. Article 35 of the Patent Law aims to protect the rights of the employer and the employee and adjust the interest between them in relation to the ownership and use of the right of receiving a patent for an invention made for hire and a patent right (hereinafter "the right of receiving a patent") on the assumption that the right of receiving a patent originally belongs to the employee who made such invention (see Article 29, paragraph 1 of the Law). Namely, the Law provides that (1) the employer has a license for the patent related to an invention made for hire by the employee (Article 35, paragraph 1); (2) articles providing for succession by the employer of the right of receiving a patent are held invalid for inventions by the employee other than the invention made for hire (paragraph 2), while, on the other hand, such articles are held valid for the invention made for hire; (3) the employee is entitled to receive payment of reasonable consideration if he assigns to the employer the right of receiving a patent for an invention made for hire (paragraph 3); and (4) the amount of consideration shall be determined considering the amount of profits receivable by the employer from the invention and the level of contribution made by the employer to the invention (paragraph 4). According to the above, the employer may include in office regulations or other rules set in advance by the employer (hereinafter "Office Regulations") a provision that the employer succeeds to the right of receiving a patent, and may not be prohibited from providing that consideration is paid for the succession, and the amount and the date of payment of the consideration, regardless of whether the employee has the intention of assigning to the employer the right of receiving a patent for an invention made for hire. However, it is clear that the amount of consideration cannot be firmly set in advance before an invention made for hire is made, or the contents and value of the right of receiving a patent to be assigned are not specific. It cannot be held that such is permissible according to the intent and contents of the provisions of the Article referred to above. In other words, the consideration set by the Office Regulations cannot be deemed to constitute all of the reasonable consideration but a part thereof under Article 35, paragraphs 3 and 4. The amount of consideration can be interpreted to constitute all of the reasonable consideration under Article 35, paragraphs 3 and 4 only if the amount of consideration matches the intent and contents of paragraph 4. Therefore, it is reasonable to interpret that the employee, who assigned to the employer the right of receiving a patent for an invention made for hire according to the Office Regulations, may claim payment of a deficiency from the employer under Article 35, paragraph 3 if the amount of consideration provided in the Office Regulations is less than the amount of consideration determined according to Article 35, paragraph 4.
2. In this case, as stated in Part I, section 2 above, the Appellant's Rules provide, among others, that the employee shall assign to the employer his right of receiving a patent for an invention made for hire, that the appellant shall give to the employee a reward for receiving income from industrial property rights if the appellant receives such income, and that the amount of such reward shall not exceed ¥ 1,000,000. The appellee received rewards for the Subject Invention accord-

ing to the Appellant's Rules. Then, if the amount of reasonable consideration under Article 35, paragraphs 3 and 4 of the Patent Law exceeds the amount of consideration provided in the Appellant's Rules, the appellee may allege this point and claim payment of a deficiency.

3. The judgment of the initial court mentioned in Part I, section 3(1) above indicates the above and thus is acceptable. The appellant's arguments merely criticize the original judgment based on its unique opinion, and are not acceptable.

Part III. Concerning Reason 3

1. In the event that there are Office Regulations providing that the right of receiving a patent for an invention made for hire shall be assigned to the employer, the employee shall obtain the right of receiving payment of reasonable consideration when he assigns the right of receiving a patent to the employer (Article 35, paragraph 3 of the Patent Law). Paragraph 4 of that Article provides for the amount of consideration. Thus, if the amount under the Office Regulations is less than the amount calculated under paragraph 4, the latter shall govern. But there is not any rule about the payment date of the consideration. Therefore, if the Office Regulations set the payment date of the consideration, it is held that the law prohibits the employee from exercising his right of receiving payment of the reasonable consideration, and that the employee cannot claim payment thereof, until the payment becomes due under the Office Regulations. Then, if the Office Regulations include a provision related to the payment date of the consideration payable from the employer to the employee, it is reasonable to interpret that the date of payment shall be the starting point of the period of extinctive prescription of the right of receiving payment of the reasonable consideration.
2. In this case, as stated in Part I, section 2 above, the Appellant's Rules provide that the appellant shall give to the employee a one-time reward for 2 years from the date of receiving income from industrial property rights if the appellant continuously receives such from a third party, and the appellee received royalties for the Subject Invention in and after October 1990. Then, the date of payment of the reward under the Appellant's Rules shall be the starting point of the period of extinctive prescription of the right of receiving payment of the reasonable consideration in this case. Therefore, the period of extinctive prescription of the appellee's right clearly did not pass until March 3, 1995 when the appellee initiated the subject proceedings.
3. The judgment of the initial court related to the appellant's argument stated in Part I, section 3 (2) above is legitimate in its conclusion. The original judgment does not contain any unlawfulness alleged by the appellant. The appellant's arguments are not acceptable.

Accordingly, it is judged as stated in the text based on the judges' unanimous opinion.

Chief Justice: Toyozo Ueda
Justice: Toshihiro Kanatani
Justice: Kunio Hamada
Justice: Tokiyasu Fujita

Recent Court Case in Pharmaceutical Field

Introduction

This article concerns a case wherein after expiration of a substance patent of an original drug, the plaintiff who owns a patent for a crystal form of the original drug requests an injunction on the defendant's generic drugs and payment of damages under the assertion that the generic drugs infringed the crystal form patent. The same plaintiff had sued ten generic drug companies at the Tokyo and Osaka District Courts, but the Courts dismissed the plaintiff's claims on 31 January, 7 May and 29 May 2003 (Case Nos. 2002 (wa) 6608, 8785, 6613 and 4040). There is a likelihood that such lawsuits will increase in number in Japan, since several substance patents of mega-selling original drugs are set to expire within a few years.

Case No. 2002 (wa) 3043

Osaka District Court, Decided 30 January 2003
Richter Gedeon Vegyeszeti Gyar R.T. v. Towa Pharmaceutical Co., Ltd.

The plaintiff's claims are dismissed.

[Claims]

1. Defendant should not manufacture, sell, or display for the purpose of sale any of the articles appearing in the attached list.
2. Defendant must destroy all articles belonging to them that are indicated in the attached list.

[Facts]

Patent at issue

The parent application, which contains three inventions, (i) form "A" of famotidine, (ii) form "B" of famotidine and (iii) method of preparing form "A" of famotidine, was filed on 4 August 1987. A divisional application directed to form "B" of famotidine was filed on 5 December 1995 and registered for patent at issue (JP 2708715).

Claims 1 and 2 of the patent at issue read as follows:

1. *Form "B" of famotidine which has an endotherma maximum of melting at 159°C on the DSC; its characteristic absorption bands in its infrared spectrum are at 3506, 3103 and 777 cm⁻¹; and its melting point is 159-162°C.*
2. *A method for preparation of morphologically homogeneous famotidine, which comprises dissolving famotidine of optional morphological composition in water and/or lower aliphatic alcohol under heating and in the case of the preparation of form "B", the product is precipitated from its oversaturated solution, which was oversaturated at a temperature at 40°C or lower and separating the required product from the obtained suspension of crystals.*

Constituent features of the patented invention

The patented invention of claim 1 has the following constituent features (i)-(iii):

- (i) an endotherma maximum of melting at 159°C on the DSC

(differential scanning calorimetry);

- (ii) characteristic absorption bands in its IR spectrum at 3506, 3103 and 777 cm⁻¹; and
- (iii) a melting point of 159-162°C.

Crystal forms of famotidine

Famotidine has two crystal forms, form "A" and form "B".

Prior art of famotidine

Yamanouchi Pharmaceutical Co., Ltd. developed famotidine and obtained patents (JP 56-22770, JP 56-55383 and JP59-227870) for famotidine and a method for producing it. Based on the present knowledge that famotidine has two crystal forms, form "A" and form "B", the famotidine disclosed in the Yamanouchi's patents is recognized to be a mixture of forms "A" and "B".

Approval to manufacture the defendant's drug

The defendant obtained on 15 March 2002, approval under Article 14-1 of the Pharmaceutical Affairs Law to manufacture a generic drug of "Gaster tablets"; and obtained on 12 March 2002, approval to manufacture a generic drug of "Gaster powder". "Gaster" containing famotidine is an H2 receptor antagonist and has been manufactured and sold by Yamanouchi, a licensee of the patent at issue.

The defendant applied for National Health Insurance (NHI) price listing and is preparing to sell the generic drugs as NHI approved drugs. Once a drug is listed in the NHI price list, sales of that drug must commence within 3 months from the date of it being listed, as provided for under administrative direction. Drug listing is conducted in the period of early July each year. Thus, if the defendant's drugs are carried in the NHI price listing in early July of 2003, the defendant is required to commence sales of the drugs within 3 months of that time.

Famotidine in the defendant's drugs

When applying for approval to manufacture a drug which contains an ingredient listed in the Japanese Pharmacopoeia, the ingredient must satisfy the standards provided for in the Japanese Pharmacopoeia. Therefore, the famotidine contained in the defendant's drugs is the famotidine of the Japanese Pharmacopoeia.

Description of famotidine in Japanese Pharmacopoeia

1. In the general notices (page 3) of the Japanese Pharmacopoeia (14th Edition) the following is stated:

Drugs are to be tested according to the provisions given in the pertinent monographs, etc., for their conformity to the Japanese Pharmacopoeia. However, the odor, taste, crystal form, solubility.....and melting point under Description.....are given for information, and should not be taken as indicating standards for conformity.

2. Under "Description" of "Famotidine" of the Japanese Pharmacopoeia (page 1816), it is stated that "this drug is in a white to yellowish white crystal form" with "a melting point of about 164°C (with decomposition)".

Under "Identification Test" on "Famotidine" in the Japanese Pharmacopoeia (page 1817), it is stated that "when comparing the IR absorption spectrum of the drug with the reference spectrum of famotidine, the spectra exhibit absorption of a similar

intensity at the same wavelength”.

History of opposition against EP patent

Merck and Yamanouchi filed an opposition against the corresponding EP patent (EP 256747), asserting that a famotidine product sold before the priority date of EP 256747 contained form “B” of famotidine. The opposition division decided that the invention of EP 256747 was worked publicly and thus lacked novelty. The patentee filed an appeal against the decision.

The board of appeals decided that the invention of form “B” lacked novelty since it was the same invention as that described in Reference Example 4 of EP 128736.

[Issues]

- (1) (a) Whether the patented invention is directed to famotidine solely consisting of form “B” (100% pure form “B”).
- (b) Whether the famotidine listed in the Japanese Pharmacopoeia is form “B” to which the patented invention is directed.
- (c) Whether the defendant’s drug is covered by the technical scope of the patented invention.
- (2) Whether the patented invention should be invalidated for the reason that it was publicly worked in Japan or other countries before the priority date.
- (3) Whether enforcement of this patent constitutes an abuse of the patent right for the reason that the patented invention merely specifies the physical properties of famotidine and does not show any of its advantages as a drug.

[Summary of Court’s statements]

Regarding issue (1) (a)

1. The patented invention is directed to form “B” of famotidine. The meaning of form “B” is in dispute between the plaintiff and defendant. The plaintiff alleges that an equivalent of form “B”, which contains a small amount of form “A”, should be covered by the patented invention. The defendant alleges that the patented invention only covers famotidine consisting of 100% form “B”.

From the description of the claims it is not clear which interpretation is accurate.

It is recognized that the “detailed description” of the specification sets out the following as a premise for the claims to call for a purely “B” form famotidine and a method for preparing it:

famotidine, which was not previously known to have crystal polymorphisms, can exist in 2 crystal forms “A” and “B”;

forms “A” and “B” have different endotherma maximums of melting, IR absorption bands and melting points;

forms “A” and “B” differ greatly in physicochemical properties and bioavailability; and

the crystal forms depend on kinetic conditions of crystallization.

Therefore, it is deemed appropriate to interpret that form “B” of the patented invention is essentially a pure form which does not contain form “A”.

However, room does remain for an interpretation that a form “B” famotidine product containing a small amount of form “A” is covered by the technical scope of the patented invention, in so far as values similar to those shown for the patented

invention are measured in the product.

The specification, however, does not suggest anything about the possibility that form “A” may contain form “B” or vice versa, or how much of form “A” is contained in form “B” in providing the values for the patented invention. From the description of the specification, it is also unclear how much of form “A” may specifically be contained in form “B” famotidine. Therefore, to the only correct interpretation is that the patented invention is directed to famotidine in crystal form “B” which is pure or almost pure.

2. During examination of this patent, the applicant stated as follows in a written argument against a notice of Reason for Rejection (lack of inventive step). The statement supports the interpretation that the patented invention is directed to famotidine in form “B” which is pure or almost pure.

Form “B” famotidine has an electrostatic charging tendency 20-times higher than that of form “A”, which results in a much stronger biological adsorptive power for form “B” as compared with form “A”. In other words, form “B” famotidine is more advantageous than form “A”. This was first found by obtaining pure form “B” famotidine as accomplished by the present invention. Pure form “B” famotidine is different from and brings about a more advantageous effect than the famotidines of Citations 1-3 (mixtures of forms “A” and “B”).

A mixture consisting of compounds having greatly different physical or physicochemical properties from each other is disadvantageous in a drug manufacturing process, because if a ratio between forms “A” and “B” varies among batches, a resulting drug will exhibit uneven efficacy among batches.

Therefore, pure form “B” famotidine is also advantageous in avoiding variations among product batches. Such an advantage could not be conceived from the disclosure of Citations 1-3.

3. The following provides other evidence for the validity of recognizing that the patented invention is directed to famotidine in form “B” which is pure or almost pure.

- (a) The plaintiff asserts that the values of IR spectrum in the constituent feature (a) indicate absorption wavelength, but do not specify an absorption intensity, as a result of which the patented invention covers not only famotidine of 100% “B” form but also an equivalent of form “B” that contains a small amount of form “A”.

However, it can not be concluded that the patented invention covers a mixture of forms “A” and “B” merely because absorption intensity is not specified.

- (b) The plaintiff says that famotidine containing about 10% form “A” in form “B” is an equivalent of form “B” and should be covered by the technical scope of the patented invention, since the characteristic absorption bands of form “A” appear in the IR spectrum only when form “A” is contained in an amount of about 15% or more.

However, this assertion can not be adopted since it is recognized from the report made by SANYO chemical laboratory that the characteristic absorption bands of form “A” appear in the IR spectrum when form “A” is contained in an amount of 5% or more.

- (c) The Plaintiff asserts that the endotherma maximum of melting on the DSC (constituent feature (i)) and melting

point (constituent feature (iii)) were used as a supplemental means for confirming that famotidine was in form "B" after identifying it as being in the novel form "B" from its IR absorption spectrum.

However, this assertion can not be accepted, since there is no passage in the specification stating or implying that the endotherma maximum of melting on the DSC and melting point were used as supplemental means of confirmation.

Regarding issue (1) (b)

1. In the Japanese Pharmacopoeia (14th Edition), the use of IR absorption spectrum is mentioned in "Identification Test for famotidine". From a comparison between the IR absorption spectrum of famotidine shown in the Japanese Pharmacopoeia and that shown in Figure 1 of "Comparison of the polymorphic modifications of famotidine" (Plaintiff's Exhibit No. 7), it is recognized that the IR absorption spectrum of famotidine in the Japanese Pharmacopoeia is more like the spectrum of form "B" than form "A".

However, this does not directly support an interpretation that the famotidine listed in the Japanese Pharmacopoeia is limited to form "B" crystals.

2. (a) From the disclosure of the specification, it is recognized that the melting point of famotidine crystals in form "B", which is pure or almost pure, is 159-162°C, whereas the melting point of famotidine crystals in form "A", which is pure or almost pure, is 167-170°C.

The Japanese Pharmacopoeia states that the melting point of famotidine is "about 164°C (with decomposition)", and this is not the same as that of form "B" or form "A", and is therefore recognized to be the melting point of a mixture of forms "B" and "A".

(b) From a report made by a deputy director of the sales department of the plaintiff (Plaintiff's Exhibit No. 20), definitions of melting points and melting ranges stated in pharmacopoeias vary among countries, and actual values of melting points and melting ranges of famotidine measured according to methods described in pharmacopoeias also vary among countries.

In the report, actual melting point values are listed. The stated values were measured according to the methods described in the Japanese and Hungarian Pharmacopoeias, respectively, on famotidine from the same product batch. Although the values obtained according to Japanese Pharmacopoeia are higher than those obtained according to Hungarian Pharmacopoeia, the difference is less than 2°C. Therefore, even if the melting point of form "B" given in the specification was the value obtained by measurement according to a method resembling the method described in the Hungarian Pharmacopoeia, there could be no reversal of the position that the melting point of 164°C indicated in the Japanese Pharmacopoeia is distinguishable from the melting point of 159-162°C (constituent feature (iii)).

3. In the opposition brief (Defendant's Exhibit No. 9) filed against the EP patent corresponding to the patented invention, Merck stated that "chemists of PR & D knew that famotidine has two crystal forms, with the white crystals having the chemical and material properties of form "B", and the pale yellow crystals corresponding to form "A". The plaintiff did not dispute this

point in the opposition, and thus it is recognized that form "B" is white and form "A" is pale yellow.

Since famotidine is described as "crystals of white to pale yellowish white" in the Japanese Pharmacopoeia, the color of the crystals of the famotidine described in the Japanese Pharmacopoeia also attests that the famotidine at issue is a mixture of forms "A" and "B".

Regarding issue (1) (c)

1. The famotidine contained in the defendant's drug is the famotidine of the Japanese Pharmacopoeia. The famotidine of the Japanese Pharmacopoeia is recognized to be a mixture of forms "A" and "B", not form "B" of the patented invention which is pure or almost pure.

Therefore, the famotidine contained in the defendant's drug is recognized to be a mixture of forms "A" and "B", not form "B" of the patented invention which is pure or almost pure.

2. The plaintiff argues that since it was impossible to control crystal precipitation of thermodynamically stable form "A" and thermodynamically unstable form "B" at a specified ratio, the defendant must have prepared form "B" using the techniques of this patented invention and form "A" using the plaintiff's another patented invention and then blended the two forms such that the resulting product would contain 5-10% of form "A" in form "B".

However, experimental reports R and Q, as well as professor T's report support the presumption that the ratio of forms "A" and "B" in a famotidine product can be controlled by appropriately selecting conditions for proceeding with crystal precipitation. Therefore, it is presumed that the defendant's famotidine is a mixture of crystals consisting of 5-10% form "A" and 90-95% form "B", and which was prepared by using a series of steps including the crystallization step.

Conclusion

In view of the foregoing, it is considered that there is no need to review any other issues to conclude that the plaintiff's claims are entirely groundless.

Keiko Kanemoto Ph.D., (Ms.);
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Court Case Review (Trademark)

Parallel import of goods bearing a registered trademark

In the FRED PERRY case, HEI-14 (Ju) 1100, the Supreme Court upheld the Osaka High Court's decision stating that the import of goods, which a licensee had produced in breach of an agreement restricting production areas and prohibiting subcontracting of production, infringing a trademark right since the import of such goods could not be recognized as a parallel import of genuine goods.

Fred Perry Holdings (hereafter referred to as "FPH"), the worldwide owner of the very famous trademarks of "FRED PERRY"

and “laurel device” (hereafter referred to as “FRED PERRY trademarks”), is a subsidiary of Hit Union K.K., the owner of the Japanese trademark right for FRED PERRY trademarks. FPH licensed a Singaporean company to produce goods bearing FRED PERRY trademarks only in Singapore, Malaysia, Brunei Darussalam and Indonesia. In the agreement, FPH prohibited subcontracting production of goods. However, the licensee subcontracted production of goods bearing FRED PERRY trademarks to a factory in the People’s Republic of China, outside the authorized production areas.

In the Tokyo High Court and the Osaka High Court, the Japanese trademark owner and importers of the goods which were produced in breach of the agreement described above, argued as to whether the import of such goods infringed a trademark right.

The Tokyo High Court judged that, even if the imported goods were produced outside the authorized production areas, the import of such goods should still be permissible as a parallel import of genuine goods on condition that (a) trademark functions including a function for indicating a source of goods was not impaired, and (b) the quality of such goods was substantially identical with the quality of other genuine goods. The Tokyo High Court also stated that it was unreasonable that such goods were not recognized as genuine goods just because of the breach of the agreement, since such a breach should remain a private issue between the licensor and the licensee, and free movement of goods would be interrupted if the goods were not recognized as genuine goods.

In contrast to the Tokyo High Court’s decision, the Osaka High Court judged that the import of goods in breach of the agreement infringed a trademark right. The Supreme Court subsequently affirmed the Osaka High Court’s decision.

The Supreme Court indicated three criteria to determine whether the import of goods bearing a registered trademark was permissible as a parallel import of genuine goods. The Supreme Court stated that, since the import did not impair trademark functions for indicating the source of goods and guaranteeing the quality of goods, and did not harm the business reputation of the trademark owner or adversely affect the interests of consumers, the import of goods bearing a registered trademark were not sub-

stantially illegal with regard to the following three criteria:

- (1) Trademark is legally applied to imported goods by a foreign trademark owner or its licensee.
- (2) Trademark of imported goods indicates a source of goods identical with that indicated by a Japanese registered trademark under the circumstances that a foreign trademark owner is identical with a Japanese trademark owner, or can be equated with a Japanese trademark owner in view of legislation or economic relation.
- (3) It is possible for a Japanese trademark owner to directly or indirectly control the quality of imported goods, so the quality of imported goods is not substantially different from that of goods of a Japanese trademark owner.

Applying the above-indicated criteria to this case, the Supreme Court confirmed that the import of goods in breach of the agreement could not be recognized as a parallel import of genuine goods, and was not permissible for the following reasons:

- (a) In this case, a trademark function for indicating a source of goods was impaired since the imported goods were produced in breach of the agreement by the licensee.
- (b) It was likely that a trademark function for guaranteeing the quality of goods would be impaired, since the imported goods were not under the Japanese trademark owner’s quality control. It was possible that there would be differences in quality between the imported goods and the Japanese trademark owner’s goods.
- (c) If the import of goods in breach of the agreement were permissible, the business reputation of FPS and Hit Union K.K. was likely to be harmed, and consumers’ trust in the quality of goods bearing FRED PERRY trademarks was also likely to be adversely affected.

The Supreme Court’s decision emphasized that the agreement for the restriction of production areas and for the prohibition of subcontracting production is very important in enabling the trademark owner to control the quality of goods, and the trademark function to effectively work.

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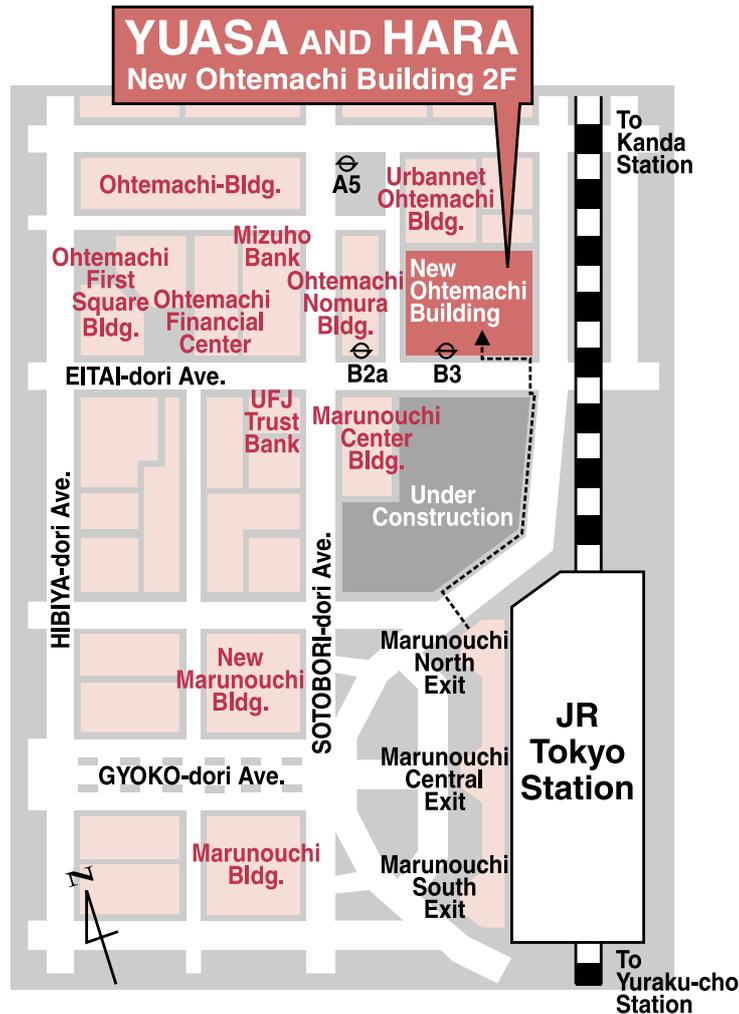
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New Map for Our Office

Due to the new construction of buildings and the change of building names around the central Tokyo area, we believe the map as indicated below will help you to find the right direction to our office located in the New-Ohtemachi Building. We hope you will not lose your way to our office when you will be in Tokyo! You can also find the direction map at

<http://www.yuasa-hara.co.jp/english/mapl/index.htm>

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