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Newsletter

In this Newsletter we explain the following:

- Additional announcement from the JPO regarding examination of PBP claims
- Revision of the Guidelines for the Management of Trade Secrets and amendment of the Unfair Competition Prevention Act
- Planned revision of the Customs Law in order to intercept products at the border that infringe on trade secrets
- Supreme Court ruling on patent term extensions based on drugs that have been approved after a change in dosage or administration only
- Revision of fees (patent and trademark)

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1 Additional announcement from the JPO regarding examination of PBP claims

The Patent Office has announced reference examples for asserting and proving the “impossible or impractical circumstances” during the examination of product-by-process claims (hereinafter referred to as PBP claims).

1. Background

As stated in the previous Circular (No. E-195), in June 2015, the Supreme Court indicated the following criteria with respect to the interpretation of PBP claims (Case Number: 2012 (*Ju*) 1204):

- (1) The scope covered by PBP claims is products with the same structure or characteristics etc. as the product produced by said process.
- (2) PBP claims only fulfil the clarity requirement when the direct identification of the relevant product from its structure or characteristics is either impossible or totally impractical (hereafter “impossible or impractical circumstances”) at the time of filing.

Immediately after receiving the Supreme Court ruling, the JPO announced information concerning the handling procedure regarding the above (2) (July 2015).

Specifically, the JPO indicated that, except when the Examiner can determine there are “impossible or impractical circumstances”, if an application includes a PBP claim, a reason for rejection will be issued wherein the product of the PBP claim is unclear, and in order to overcome this, the Applicant can take the following measures:

- (a) delete the PBP claim,
- (b) amend the PBP into a claim concerning an invention of a process for producing a product,
- (c) amend the PBP into a claim concerning an invention of a product which does not include a manufacturing process,

(d) assert and prove the existence of “impossible or impractical circumstances” in an Argument.

As the above announcement did not include a detailed explanation regarding (d), the JPO has prepared reference examples of asserting and proving the “impossible or impractical circumstances”

2. Overview of Reference Examples

The reference examples provide the following examples of assertions and proofs in which the existence of “impossible or impractical circumstances” can be approved.

Example 1

In the claim “An aromatic device comprising an aroma generation source, wherein the aroma generation source is in a state where an aromatic ingredient is present deep within an activated carbon molding but not near the surface thereof, wherein said aroma generation source is produced by heating said activated carbon molding...”, the aroma generation source is identified by its method of preparation (PBP claim).

Summary of the explanation of the Argument: Because the structure of each activated carbon differs, identification with a phrase such as “said aromatic ingredient exists only in the region deeper than or equal to XX μ m from the surface” is not possible. Even if one were to measure using scanning electron microscopy (SEM) etc., only the state of the surface can be measured, and due to volatilization of the aroma ingredient, precise data cannot be obtained even if X-ray diffraction (XRD) is used. Even if the inside of a sample of the activated carbon molding can be cut off and exposed, only the microscopic state of this specific sample can be understood.

To find an index specifying the above described feature would require repeating the above processes and measurements numerous times, and undertaking statistical processing. This requires considerable trial and error and is utterly impractical.

In addition to the above Example 1, the following Examples 2-5 are also described.

Example 2

A thin film semiconductor device comprising an active layer of an oxide semiconductor film formed on a substrate by a specific method.

As in Example 1, it is not possible to find wording which specifies the structure or characteristics pertaining to the difference with the prior art, and it is impossible or impractical to analyse and specify such structure or characteristics based on measurements.

Example 3

An oil-in-water type creamy emulsion composition for foods obtained by adding an oily solution comprising emulsifiers, a component A and a component B to a water phase and emulsifying.

Depending on the various concrete modes of the manufacturing method stated in the claims, the concrete aspects of the structure or characteristics of the produced product vary widely and as these concrete aspects cannot be comprehensively expressed, it is impossible or impractical to specify the product directly by its structure or characteristics.

Example 4

A flavor improving agent obtained from sugar cane juice through a specific process.

It is impossible or impractical to specify the product directly by its structure or characteristics as it is derived from a natural product.

Example 5

Polymerized composition prepared by a specific process.

The product is a polymer having a complicated, wide variety of structures, and it is impossible or impractical to specify it directly by its structure or characteristics.

For details of these examples including an English translation thereof please use the following address (the JPO website): http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/pdf/product_process_C151125_e/pbpc_sankourei_e.pdf

3. Our view

Taking into consideration the above mentioned Supreme Court ruling and the handling procedures announced to date by the JPO including the above reference examples, our view regarding PBP claims is as follows.

As we described in the previous circular, it is preferable to avoid the frivolous or carefree use of PBP claims, in other words, as far as is possible, it is desirable to identify the product in a product claim by its structure or characteristics.

However, cases where it is unavoidable that a PBP claim must be used or where a PBP claim is unintentionally used will occur. In such cases, although the above mentioned reason for rejection will ordinarily be issued by the JPO, it is possible for the applicant to deal with this by the above described means (a) to (d).

Among the above (a) to (d), considering the scope of protection, the amendment (c) is likely to be the most preferred as it can maintain the claim as a product claim. However, the amendment (c) may be difficult from the point of view of the addition of new matter, for example.

In such a situation, it is necessary to select another means, and if the invention relating to the corresponding claim is, as per (b), amended to a method for producing a product, then the product produced by the aforementioned method is protected by the post-amendment method claim. (In Japanese Patent Law, Article 2(3)(iii) stipulates that the patent right relating to “a process of producing a product” covers the product produced by the process, in addition to the process.)

Alternatively, opting to assert or prove the existence of “impossible or impractical circumstances”, as per (d), can also be considered. As the JPO has announced the above described reference examples, the assertion and proof may be a powerful means for solving the above reason for rejection if the PBP claim of the particular patent application corresponds to one of these examples (or is similar). If opting for (d), there is the great advantage that there is no requirement to change the contents of the claim by amendment.

It should be noted that the Examiner will consult the descriptions in the Specification before issuing the reason for rejection. Accordingly, it is advisable to specifically describe the “impossible or impractical circumstances” in the Specification as the time of filing, if such circumstances exist.

As described above, it is preferable to avoid the use of PBP claims to the extent possible; however, if an application includes a PBP claim, even if the above mentioned reason for rejection is received, depending on the content of the invention and circumstances etc., in many cases it will be possible to overcome the reason for rejection by selecting one of the above (a) to (d) appropriately (or alternatively, depending on circumstances, a combination) and suitably responding.

If, for a patent application which we handle, there is a reason for refusal regarding a PBP claim, we will be happy to consider and propose appropriate measures according to the given situation.

Revision of the Guidelines for the Management of Trade Secrets and amendment of the Unfair Competition Prevention Act

In recent years, trade secret infringement cases, such as the taking and disclosure to competitors of blueprints of apparatus by employees, the leaking of customer data and so on, have occurred one after the other. The risk of information leaks has increased due to the digitization of information. In addition, if spread through the Internet the damage will be greater once a trade secret has been illegally acquired, due to the increasing sophistication of IT. Furthermore, the value of concealment of IP (trade secrecy) is being re-evaluated as a business strategy. Hence, it was decided to strengthen protection of trade secrets by fully revising the Guidelines for the Management of Trade Secrets (effective on 28 January 2015), and expanding what is subject to punishment and toughening of the law by revising of the Unfair Competition Prevention Act. The revised Unfair Competition Prevention Act has been in effect since 1 January 2016 (certain provisions went into immediate effect at the time of promulgation).

1. Revision of Guidelines for the Management of Trade Secrets

In the past, the Guidelines for the Management of Trade Secrets were based on about 100 judicial precedents. As such, the requirements were unclear, and the realization of all items required was, in reality, difficult. Therefore, in the new Guidelines, the minimum level of trade secret management measures needed to receive legal protection was clarified. After the revision, the minimum level of management measures became “steps such that employees who can come into contact with information understand that said information is secret (reasonable means commensurate with the actual situation and size of a company)”. Specifically, the indication of the fact that “this information is secret” in the case of paper or a recording medium, or listing the tangible embodiments which should be kept secret in the case of tangible embodiments (for example, molds, etc.). In other words, the point is that it is possible to recognize that the information is secret. In addition, it is sufficient to demonstrate an intention of seeking confidentiality (for example, a fax) to business partners in order to prevent unauthorized use by said business partners, a contract being unnecessary.

2. Amendment of the Unfair Competition Prevention Act

Expansion and adjustment of the civil and criminal scope of protection

1. The unauthorized use/unauthorized disclosure of trade secrets by all persons acquiring said trade secrets knowing that trade secrets have been disclosed without authorization becomes subject to punishment (criminal penalty)

In the past, up to and including “second” subsequent acquirers were the target for criminal penalties, though civil injunctions have already been possible for all subsequent acquirers. However, after the amendment, this restriction is abolished and “third” or later subsequent acquirers are now all targets for criminal penalties.

2. Expanding the scope of overseas criminal punishment (criminal penalty)

In the past, the act of overseas acquisition of “a trade secret which is managed in Japan” was not punishable (the acts of overseas use and disclosure were punishable). However, after the amendment it has become a punishable act to acquire, use or disclose “trade secrets of owners who conduct business in Japan”. This amendment clarifies that the act of illegal acquisition in a foreign country of a trade secret stored, for example, on an overseas server (cloud etc.) owned by someone doing business in Japan is punishable.

3. The acts of assignment, import and export etc. of products that infringe on trade secrets become subject to civil and criminal punishment (excluding criminal negligence)

If a trade secret, such as a production method, is used, some kind of thing (a product) is generated. Before the amendment, the acts of assignment, import and export of a product generated by the use of a trade secret (a product that infringes on a trade secret) were not subject to regulation. Therefore, with the aim of increasing the deterrent to infringe by regulating the flow of products that infringe on trade secrets, as is the case for patent infringing goods, the assignment, delivery of products produced by the unauthorized use of trade secrets of other entities, and the display of such products for the purposes of assignment or delivery, their import/export or provision via electric telecommunication lines, have become targets of civil damages/injunction, and even added to the target of criminal penalties. However, persons who become a civil target are limited to those who fraudulently used trade secrets of other entities, the assignees who knew the products infringing on trade secrets at the time of acquisition or, even if the assignees did not know at that time, those who were grossly negligent* in failing to determine at the time of the acquisition whether the thing in question was a product that infringes on a trade secret. For criminal penalties on the other hand, only in cases where the person actually “knew” are they subject to punishment.

* “Grossly negligent” means a significant breach of diligence in business practice to the extent that can be equated with malice. For example, in the case of a company that receives a warning letter regarding said company’s products from the person asserting to be the right holder of the trade secret and then despite the specific content concerning the trade secret infringement situation described therein, the act of selling the product without any sort of enquiry or investigation.

4. The attempted act of unauthorized acquisition, disclosure and so on are also subject to punishment (criminal penalty)

Prior to the amendment, only completed acts of trade secret infringement (criminal acts and the results of these criminal acts) were subject to criminal penalties. However, due to the increasing sophistication of IT, the risk of cyber-attacks and the instantaneous diffusion of information through the Internet has increased. Accordingly, in response to the changed IT environment, even a failed attempt, such as those described below, has become subject to punishment.

- Although the act of unauthorized access has been confirmed, the fact that a trade secret has been taken cannot be confirmed due to destruction of evidence etc. (attempted acquisition).
- Using the account of a company email system administrator to embed a program to automatically transfer company executive emails to oneself. However, these facts become apparent before the trade secret information is actually transferred (attempted acquisition).
- Attempting to produce products in accordance with a blueprint which is a trade secret acquired without authorization. Although a production line was assembled and the machinery operated, the machinery failed before the product was completed (attempted use).
- Sending by email an improperly acquired trade secret, which was first sold over the telephone, but which does not reach the addressee due to a fault in the email software (attempted disclosure).

The question of whether an act corresponds to an “attempted act” or not is whether the act can be evaluated as having had a realistic risk of compromising a trade secret. The act of a person such as an employee who has been legitimately shown a trade secret, of improperly misappropriating, reproducing etc. (stealing) this trade secret is not an “attempted act”.

Strengthening of penalties aimed at improving deterrence

Given the rising value of trade secrets and the increase in concern about infringement, it has been decided to improve deterrence by raising the statutory penalty for the natural person who commits the act and for the judicial person backing them (the principal offender).

1. Raising the upper limit for fines (criminal penalties)

| | Pre-Amendment | Post-Amendment |
|------------------|--|--|
| Natural Persons | Imprisonment: 10 years, Fine: JPY10,000,000 (Both possible) | Imprisonment: unchanged Fine: JPY20,000,000 (Both possible) Heavier fine for cross border cases: JPY30,000,000 (Both possible) |
| Judicial Persons | Fine: JPY300,000,000 | Fine: JPY500,000,000; Heavier fine for cross border cases: JPY1,000,000,000 |

2. No complaint from victim needed for prosecution of trade secret infringement (civil)

Previously, a complaint was required from the victim for prosecution of trade secret infringement, but no complaint is now needed. This is in light of the need for protection, etc. of aspects of trade secrets of public interest such as trade secrets shared with other companies, customer lists, and so on.

3. Introduction of optional forfeiture provisions (natural persons, judicial persons)

Before the amendment, there was no system to confiscate criminal proceeds. However, a provision has been newly introduced wherein forfeiture of criminal proceeds obtained by the crime of trade secret infringement is possible with the judgment of the court. There is no upper limit for the forfeit amount. In addition, if these proceeds cannot be forfeited due to having already been expended, a penalty of equivalent value can be imposed. Examples of assets that are subject to forfeiture include: assets that were obtained in return for illegally taking a trade secret, and products produced by unauthorized use of a trade secret themselves or the total sales obtained by sale of these products.

Improving the effectiveness of civil remedies

1. Reduction of the burden of proof in the claim for damages, etc. (introduction of rebuttable presumption)

In the past, the plaintiff (victim) was required to prove that the defendant (perpetrator) (1) illegally acquired the plaintiff's trade secret technology, (2) has done business in an area which involves this technology and (3) has used this technology. After the amendment, (3) is *a priori* assumed and the burden of rebutting falls on the defendant.

2. Extension of the statute of limitations

The statute of limitations of the right to seek injunction against unauthorized use of trade secrets has been extended from 10 to 20 years.

3 Planned revision of the Customs Law in order to intercept products at the border that infringe on trade secrets

After receiving the current amendment of the Unfair Competition Prevention Act, the Ministry of Finance solidified the plans to submit the proposed revision of the Customs Law in the next Parliament. Under the current law, even if for example products that infringe on trade secrets are discovered, the Customs cannot directly seize and dispose of these products. Therefore, the current situation is that Customs can only report to, and thereafter rely on, the police and the Ministry of Economy, Trade and Industry. Therefore, it is expected that the revision will specify products that infringe on trade secrets as targets for the border injunction system (import and export of banned items) in Customs, and will make possible the seizure and disposal at the time of import/export based on the judgment of the Customs, and in addition, make possible the investigation of a suspicious product when it is discovered. The relevant ministries and agencies are currently assessing the specific procedures etc.

We will notify you if there are any developments regarding the revision of the Customs Law in order to intercept products at the border that infringe on trade secrets.

4 Supreme Court ruling on patent term extensions based on drugs that have been approved after a change in dosage or administration only

The Supreme Court has issued a judgment regarding the extension of the duration of a patent right which negated the JPO Examination Guidelines and practice used until now (Case Number: 2014 (*Gyo-Hi*) 356; Date of the Ruling: 17 November 2015). This judgment indicated that if a pharmaceutical, which differs from a pharmaceutical which has already received the required government approval in only dosage and administration, gains approval, the extension of the duration of the patent right based on the new approval should be approved even if the related patent right does not have the subject matter related to dosage and administration.

In Japan, extension of a patent right relating to an agricultural chemical or a pharmaceutical of up to five years is recognized when there is a period of time when the patented invention cannot be worked because of the necessity to obtain government approval.

Genentech Inc. received approval in 2007 for their anticancer agent “Avastin” (generic name: bevacizumab) and received additional approval for a different dosage and administration regime thereof in 2009. Based on the approval they received in 2009, Genentech Inc. submitted an application for an extension of the duration of JP3398382 (11 claims. Claim 1 is shown below). However, the decision of the JPO in the Appeal Trial was that it does not approve the extension on the grounds that it was possible to work the invention because of the 2007 approval and hence the 2009 approval was not necessary to work the invention. Genentech Inc. then filed a lawsuit seeking the cancellation of the decision of the JPO.

➤ Pharmaceutical that was approved in 2007

Active ingredient:

Bevacizumab

Effectiveness and efficacy:

Unresectable advanced or recurrent colorectal cancer

Dosage and administration:

In combination with other anticancer drugs, adults are ordinarily infused intravenously with bevacizumab at a dose of 7.5 mg/kg (weight) with a dosing interval of at least 3 weeks.

➤ Pharmaceutical that was approved in 2009 (hereafter referred to as “the present pharmaceutical”)

As above, except at a dose of 5 or 10mg/kg (weight) with a dosing interval of at least 2 weeks.

• Claim 1 of JP3398382B

A composition for treatment of cancer comprising a therapeutically effective amount of an hVEGF antagonist which is an anti-VEGF antibody.

In the current JPO Examination Guidelines and Examination Practice, if a patent term extension application is made based on the approval (hereafter “the present approval”) of a pharmaceutical and a pharmaceutical has been approved prior to this approval, and the two approvals are the same from the point of view of the subject matter described in the patented invention, the JPO determines that it was possible to work the patented invention even without the present approval because of the earlier approval. In other words, the present approval is not necessary for the working of the present invention.

In the present case in accordance with such criteria, the JPO determined that if, from the point of view of the subject matter described in claim 1 of the patent (i.e. hVEGF antagonist and treatment of cancer), the 2007 approved pharmaceutical and the 2009 approved pharmaceutical are compared, they are the same in terms of “bevacizumab” and “unresectable advanced or recurrent colorectal cancer”. Consequently, they determined that the invention of claim 1 was already workable due to the 2007 approval regardless of the 2009 approval. (They also determined that the other claims were similarly already workable).

However, the Supreme Court ruling indicated that whether or not the present approval was necessary to work the patented invention should be determined by comparing the present approval and the prior approval, and not by a comparison from the point of view of the subject matter in the patented invention. In addition, when comparing the present approval and the prior approval, the matters directly concerning the substantial identity as pharmaceuticals should be compared (in this case, they should be compared from the point of view of the component, quantity, administration, dosage, effectiveness and efficacy of the pharmaceuticals).

And hence, the above ruling judged that due to the 2009 approval, which concerned a pharmaceutical differing in dosage and administration from the 2007 approved pharmaceutical, it became possible to produce and sell the present medicament for combination therapy of XELOX and bevacizumab for the first time, and consequently, the above JPO decision is illegal.

This ruling indicates that it is possible to extend the duration of a patent on the basis of the additional approval of a pharmaceutical which has already received approval even if only dosage and administration have changed, and potentially broadens the patents which can receive a patent term extension.

After receiving the above ruling, the JPO announced that it will revise the related Examination Guidelines, and has scheduled their publishing for spring 2016. Though they have not been published at the time of writing, we will inform you of these new Guidelines when they become available.

5 Revision of fees (patent and trademark)

The JPO fees for patents and trademarks will be revised on 1 April 2016.

Compared to the previous JPO fees, the following fees will be reduced:

Patent: Application fee, registration fee and annuities

Trademark: Trademark registration fee, renewal fee, individual fee for a trademark right based on an international registration

The revised fees will be applied for the above fees paid after 1 April 2016.