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Newsletter

As we announced in the previous newsletter, the Patent Law, Design Law, Trademark Law and related laws will be revised. The contents of the revisions are described below. The date the revised laws will be effective from is 1 April 2015 (with the exception of the Design Law revision, the effective date of which is 13 May 2015).

In addition, we describe the recent revision of the patent lifetime extension system.

April 2015

Circular No. E-194

1 Patent Law Revision (Establishment of Patent Opposition System)

As we announced in the previous newsletter, the revision of the Patent Law will establish a Patent Opposition System.

It will be possible for anyone to utilize the Patent Opposition System, providing they do so within the six months following issuance of the Patent Gazette.

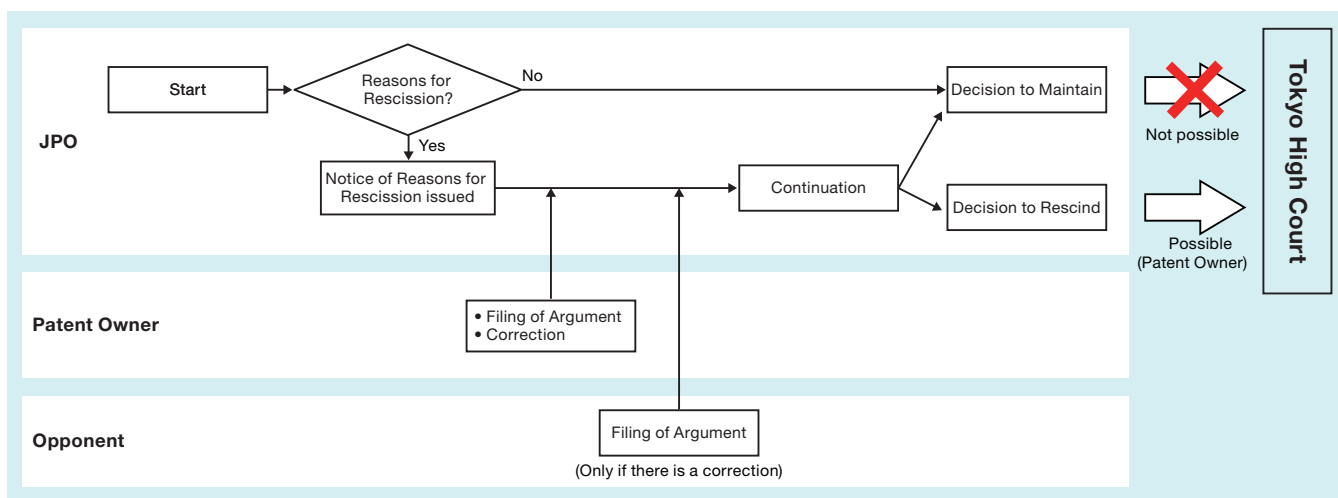
The following table provides a comparison of an overview of the soon to be introduced Patent Opposition System with Patent Invalidation Trials and Third Party Observations, which are other methods which a third party can employ against a patent application or patent.

	Patent Opposition	Patent Invalidation Trial	3rd Party Observation*1
Possible Period of Opposition / Demand / Observation	Within 6 months following issuance of the Patent Gazette	Any time after establishment of the patent right (even after lapse of patent right)	Any time for pending applications (also any time in the duration of a patent*2)
Opponent / Demandant / Submitter	Anyone (anonymity not possible)	Interested parties*3 (limited to interested parties by the current revision, with the introduction of the Patent Opposition System)	Anyone (anonymous submission of observation possible*4)
Grounds for objection / invalidation / rejection (For the sake of brevity, only typical grounds are described)	<ul style="list-style-type: none"> • Addition of new matter (Art. 17^{bis}(3)) • Lack of novelty or inventive step (Art. 29) • Prior art effect (Art. 29^{bis}) • Double patenting (Art. 39) 	<ul style="list-style-type: none"> • Addition of new matter (Art. 17^{bis}(3)) • Lack of novelty or inventive step (Art. 29) • Prior art effect (Art. 29^{bis}) • Double patenting (Art. 39) 	<ul style="list-style-type: none"> • Addition of new matter (Art. 17^{bis}(3)) • Lack of novelty or inventive step (Art. 29) • Prior art effect (Art. 29^{bis}) • Double patenting (Art. 39)

	Patent Opposition	Patent Invalidation Trial	3rd Party Observation*1
Grounds for objection / invalidation / rejection (For the sake of brevity, only typical grounds are described)	<ul style="list-style-type: none"> • Violation of enablement / support requirement (Art. 36(4)(i), 36(6)(i)) • Lack of clarity (Art. 36(6)(ii)) 	<ul style="list-style-type: none"> • Violation of enablement / support requirement (Art. 36(4)(i), 36(6)(i)) • Lack of clarity (Art. 36(6)(ii)) • Reasons relating to attribution of rights, e.g. Joint application violation (Art. 38) 	<ul style="list-style-type: none"> • Violation of enablement / support requirement (Art. 36(4)(i), 36(6)(i)) • Lack of clarity (Art. 36(6)(ii))
Unit of objection / demand	Objection per claim possible	Demand per claim possible	—
Responsible body	Appeal Examiners	Appeal Examiners	—
System	Examination of documentation*5 (no oral proceeding)	Oral proceedings, in principle	—
Involvement of patent owner	Full participation in proceedings Submission of Argument and Correction possible, if there is a Notification of Reasons for Rescission	Full participation in proceedings	—
Involvement of Opponent / Demandant / Submitter	Can file an Argument concerning the corrected invention, if a correction is demanded by the patent owner	Full participation in proceedings	Not possible
Withdrawal of opposition / demand	Possible prior to Notification of Reasons for Rescission	Possible before decision made final and binding (however, after a Written Reply has been filed, the consent of the other party is necessary)	—
Litigation in response to JPO decision	Only patent owners who receive a Decision to Rescind can file a lawsuit at the Tokyo High Court (filing an appeal against a Decision to Maintain is not possible)	Both demandant and patent owner can file a lawsuit at the Tokyo High Court	—

indicates items related to the current revision.

- *1 The Japanese system of Third Party Observation permits a third party to supply information concerning reasons for refusal such as novelty and inventive step to the JPO (typically prior art describing publications). All information provided before the commencement of the examination or while the examination is on-going will be passed to the responsible Examiner. However, the third party that provided the information cannot be directly involved in the examination. For example, even after providing the information, it is not possible to explain this information in an interview. However, those that provide information can receive feedback whether it was used in the Notice of Reasons for Refusal, if desired.
- *2 Even if a Third Party Observation is made after grant of patent, the Patent Owner is only notified thereof, and there is no examination or re-examination of the patent.
- *3 Whether or not the Demandant of the Patent Invalidation Trial corresponds to an “Interested Party” will be judged separately for each case. In previous court cases, the following have been recognized as interested parties: For example, those that are actually sued for patent infringement, those that own a similar patent, and those who manufacture the same type of product as the patented invention.
- *4 If a Third Party Observation is made anonymously, it is not possible to receive the above described feedback. In such a situation, if requested, we can watch the prosecution of the application and notify you whether a Notice of Reasons for Refusal is issued and if the information provided was used therein.
- *5 The following is a flowchart showing the typical procedures of Patent Opposition.



Patents published in the Patent Gazette issued after 1 April 2015 will have the above revision applied to them and will be opposable with the Patent Opposition System.

2 Revision of the Design Law

As we informed you in the previous issue, the Design Law will be revised based on the accession of Japan to the Geneva Act (“Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs”). The effective date of the revised Design Law will be the date on which the Geneva Act takes effect in Japan which is 13 May 2015.

Points to consider if specifying Japan in the international application

The current revision of the Design Law is intended to accommodate international applications within the framework the Design Law of Japan, and there is no change to the prior design system itself. In Japan, all design applications are subject to a substantive examination. The practices of the JPO are fairly strict and it may be difficult to make any amendments following application and therefore, whether an international application or an ordinary Japanese application should be filed should be given careful consideration. Please also be aware that some of the recognized Locarno design classifications are not recognized by the JPO, and these will not be registered in Japan even though an international application is made. Please contact us should you have any questions regarding this or any other point.

1. Multiple Design Applications

Specifying Japan through the Hague Convention	Filing directly in Japan
For an international design application which includes multiple designs, each design in the application will be considered as a single, independent design application, in line with the Japanese system of “one application, one design”. The fees (both application fee and five year registration fee) at the time of filing will thus increase according to the number of designs included in the international application.	Because of the Japanese system of “one application, one design”, it is necessary to file an application for each design. An Official Action will be issued for any design application which includes multiple designs. At the time of filing, only filing fees are paid.

2. Time When Design is Published

Specifying Japan through the Hague Convention	Filing directly in Japan
As a general rule, application content is published and viewable by third parties six months after international registration.	As a general rule, designs are undisclosed prior to their publication following establishment of design right. With some exceptions, the content of design applications that, due to being abandoned, due to a Decision of Rejection or due to a Trial Decision, did not lead to registration are not made available to third parties.
<p>Deferment of publication is possible (up to a maximum of 30 months) but the secret design system cannot be used:</p> <p>As international registration and publication are prerequisites for international applications seeking protection in Japan, the secret design system cannot be used. When deferment of the international publication is requested, then until the publication occurs, no rights are derived from the application and the examination is not done. The acquisition of rights is thus delayed accordingly.</p> <p>In addition, proceedings before the JPO, such as filing an Amendment, conversion of application, etc., are not possible until after international publication.</p>	<p>Use of secret design system is possible:</p> <p>If requested at the time of application or payment of registration fee, a design will remain undisclosed for a maximum of three years after establishment of design right. The period of secrecy is specifiable and adjustable (lengthening or shortening) during the existing period of secrecy.</p> <p>In order to exercise the rights based on the design right during the period of secrecy, it is necessary to give a warning in advance showing the content of the secret design.</p> <p>Proceedings such as filing a Voluntary Amendment, etc. are possible immediately after application.</p>
<p>If it is desired that the effects of the application are secured as quickly as possible while the design remains <u>undisclosed</u>:</p> <p>Depending on the schedule of the product announcement and launch, it may be desirable to keep a design undisclosed for a specified period of time. Therefore, we recommend that an ordinary Japanese application be filed claiming priority based on the international registration if the international registration is a first country application and the publication of which is deferred. If the examination in Japan proceeds smoothly, and there is a Decision of Design Registration registered before international publication, you can make a request to use the secret design system. Alternatively, if Japan is the first country in which the application is made, then it is also possible to file an international application on this basis.</p>	

3. Infringement (counterfeiting) by third parties prior to grant of design right

Specifying Japan through the Hague Convention	Filing directly in Japan
<p>The international publication of a design occurs before the design right is granted in Japan, leaving open the possibility of counterfeiting by a third party. If advance warning is given after international publication before establishment of the design right, it may be possible to claim compensation from the third party once the design right is established, for the period going back to the warning. However, damages cannot be claimed for this period. It is not possible to seek an injunction before the establishment of the design right.</p> <p>Note that there is no right to request compensation prior to international publication of a design, and thus the design is in an unprotected state during the period before publication.</p>	<p>Because a design is first published after the grant of the design right, the concern that it is infringed (counterfeited) by a third party before registration is small and consequently the claim compensation system does not apply. It is possible to reduce the risk of counterfeiting by timing the filing of the application in consideration of the product announcement and launch time period.</p>

4. Reasons for Refusal

Specifying Japan through the Hague Convention	Filing directly in Japan
<p>Each design in an international design application which contains multiple designs will be examined independently. Therefore, the date of notification of the Examiner's decision for each design may differ.</p> <p>In Japan, it can be expected that an Official Action will be issued for international applications 12 months after the international publication. As Official Actions will be sent from the JPO to the applicant via the International Bureau (IB), there is the possibility that there will be insufficient time for the Japanese representative to respond to the JPO. Generally, it can be said that international applications are not well suited to designs for products, the fashion for which is relatively time limited.</p>	<p>Currently, the time from filing to the first Official Action is, on average, less than 6.5 months. Because the JPO notifies the Japanese representative of the Official Action directly if the Applicants are foreign entities, there should be sufficient time to amend drawings, and so on, in order to overcome the reasons for rejection. It can be considered that if an Official Action is not issued, the time taken to the grant of the design right is faster than would be the case for the equivalent international application.</p>
<p>The contents of the Official Action are recorded in the International Register and any person who pays the relevant fee can obtain a copy of said contents from the IB.</p>	<p>The contents of Official Actions are not published. If the design is registered in the appeal stage then the Trial Decision, including a summary of the reasons for refusal, is published.</p>

5. Amendment of Figures

Specifying Japan through the Hague Convention	Filing directly in Japan
<p>If the figures of an international application do not meet the requirements of the JPO and the design cannot be identified, submission of additional figures will be requested. Similarly to ordinary Japanese applications, six sectional figures (front, rear, top, bottom, left and right view) are required. When additional figures result in a change in the gist of the design, the Amendment will be rejected. Of course it goes without saying that the grant of design right is delayed if there is an Official Action.</p>	<p>In order to clarify the content of design rights, the requirements of the figures / photos have become stricter. In principle, six sectional figures (front, rear, top, bottom, left and right view) must be filed. In order to avoid a "deficiencies in figures" Official Action, it is possible for the figures to be reviewed by a patent attorney and adjusted in advance before filing in order that they comply with Japanese practice.</p>

6. Registration and Renewal Fees

Specifying Japan through the Hague Convention	Filing directly in Japan
<p>As the registration fee for five years is paid at the time of application, the design right is established automatically in the event that the JPO issues either a Decision of Design Registration or a Trial Decision to the effect that a design is to be registered. If international applications do not result in registration in Japan, the registration fee for five years can be refunded to the payer should they make a request therefor within a specified time period.</p> <p>The period of protection of rights is 20 years from the day of registration at the longest, i.e. the same as ordinary Japanese applications. The renewal fees are the same as an ordinary Japanese application but paid every five years.</p>	<p>The payment of the registration fee is made after the Decision of Design Registration. The design right is established following this payment.</p> <p>For payment of annuities, it is possible to pay one year or more than one year together. The period of protection is 20 years from the day of registration at the longest.</p>

3 Revision of the Trademark Law - System of Protection for New Trademarks -

As reported in the previous issue, the revised Trademark Law, which will come into force on 1 April 2015, will protect new types of trademarks. In this issue, we offer a more detailed overview as well as some specifics of the application process.

1. New Types of Trademarks

The revision will make registration of the following trademarks possible

- 1. Motion trademarks: Marks in which characters, figures etc. change with time (e.g. on a TV, computer screens etc.)**
- 2. Hologram trademarks: Marks in which characters, figures etc. change via holography or other method (e.g. letters, figures etc. which change depending on the viewing angle)**
- 3. Color trademarks: Marks consisting of a single color or a combination of colors (e.g. the coloring used in the packaging of a product or advertising signage etc.)**
- 4. Sound trademarks: Marks consisting of music, voice, or natural sounds etc. and which are aurally recognized (e.g. sound logos used in commercials, the startup sound of computers etc.)**
- 5. Position trademarks: Marks which are figurative etc., and which are identified by their position on the product bearing them (e.g. a device mark in a specific position on a pocket etc.)**

Substantive examinations will also be carried out for the new types of marks

- If the characters, figures, etc. which comprise a “motion trademark”, “hologram trademark” or “position trademark” do not have the ability to distinguish the goods and/or services from others, it will in principle be judged that the entirety of the mark also does not have this ability.
- Color marks will in principle be judged to lack the ability to distinguish the goods and/or services from others.
- Sound marks consisting of elements which are, for example, sounds recognized as those ordinarily emitted by a product, monotonous and/or natural sounds, or sounds which are recognized only as a musical composition will in principle be judged to lack the ability to distinguish the goods and/or services from others.
- If judged to lack the ability to distinguish the goods and/or services from others, registration is possible if such ability can be proved to have occurred through use.
- When examining the similarity of marks, marks which are of a different type can be considered similar if there is a likelihood of confusion regarding the origin.

2. Right of Continued Use

For new types of trademarks which have been in use from before the effective date of the revision, the continuation of the use within the previous range of business will be possible even if not registered. However, this is not the case for position trademarks, as these only specify the position of a potentially conventionally registerable mark.

3. Application Method

- For the newly protectable trademarks, it will be necessary to specify the type. It will not be possible to file a single application which specifies a plurality of types, for example, a combination of motion and sound.
- For motion trademarks, hologram trademarks, color trademarks and position trademarks, a detailed description will be necessary. For sound trademarks, a sound file will be necessary.

(The following example cases introduced below are excerpts from the draft revision of the “Examination Guidelines for Trademarks” published by the JPO in February 2015.)

1. Motion Trademarks

1. Content of [Trademark for which registration is sought]

- One or more figures or photographs which show the changes in the state of the trademark over time.

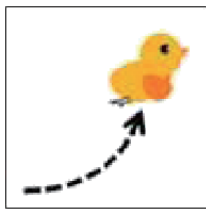
2. Content of [Detailed description of trademark]

- Concrete, clear explanation of the elements constituting the trademark and their changes with time (e.g. the order of the change, the total time required).

3. Approved example of a motion trademark

(Ex. 1) Example description using a single figure (where the mark moves without the mark itself changing)

[Trademark for which registration is sought]



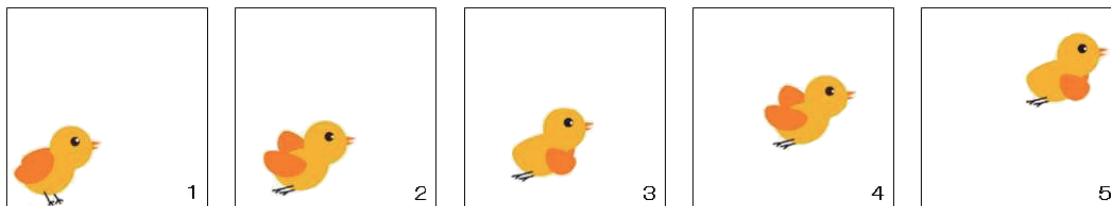
[Motion trademark]

[Detailed description of trademark]

The trademark for which registration is sought (hereafter referred to as the “trademark”) is a motion trademark which indicates the state of change of the trademark over time. A bird gradually moves from the lower left to the upper right in accordance with the dashed trajectory line. This motion trademark lasts for a total of three seconds. Note that the dashed arrow is intended only to represent the trajectory of the bird for convenience, and does not constitute an element of the trademark.

(Ex. 2) Example description using multiple different figures (where the mark moves and the mark itself changes)

[Trademark for which registration is sought]



[Motion trademark]

[Detailed description of trademark]

The trademark for which registration is sought (hereafter referred to as the “trademark”) is a motion trademark consisting of five figures which indicate the state of change of the trademark over time. Note that the numbers displayed in the lower right corner of each figure indicate the order of the figures, and do not constitute an element of the trademark. Across Figures 1 to 5, the state of gradual motion of the bird from the lower left to the upper right is represented, in which the bird in Figure 1 has closed wings, raised wings in Figure 2, lowered wings in Figure 3, raised wings in Figure 4 and lowered wings in Figure 5. This motion trademark lasts for a total of three seconds.

2. Hologram Trademarks

1. Content of [Trademark for which registration is sought]

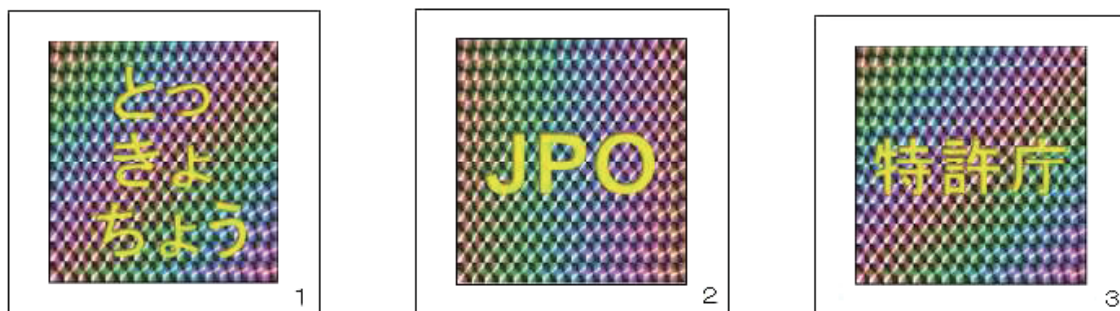
- One or more figures or photographs which indicate the different appearances of the trademark achieved by holography or other method.

2. Content of [Detailed description of trademark]

- Concrete, clear explanation of the elements constituting the mark and of the changes brought about by the holographic visual effects, or other method (e.g. seeing different content depending on the viewing angle).

3. Approved example of a hologram trademark

[Trademark for which registration is sought]



[Hologram trademark]

[Detailed description of trademark]

The trademark for which registration is sought (hereafter referred to as the “trademark”) is a hologram trademark, the displayed content of which changes depending on the viewing angle. Note that the numbering, such as “1” etc., in the lower right corner of the trademark represents the order of the figures, and does not constitute an element of the trademark. Figures 1, 2 and 3 respectively show the trademark when viewed from the left, from in front, and from the right.

3. Color trademarks



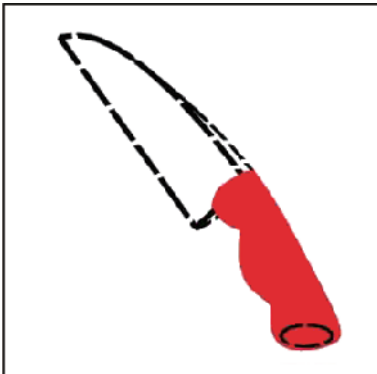
1. Content of [Trademark for which registration is sought]

- Figure or photo indicating the color for which trademark registration is sought, or if applicable,
- One or more figures or photos which indicate the color for which the trademark registration is sought and its position on the product which bears it, wherein only the part which bears the said color is shown in said color and the other parts are indicated by broken lines, etc.

2. Content of [Detailed description of trademark]

- Concrete, clear explanation of color name, mixing ratio of the three primary colors (RGB), color swatch book number, and if there is a combination of colors, how the colors are combined (i.e. arrangement and proportions of each color).

3. Approved examples of a color trademark

<p>(Ex. 1) Single color</p> <p>[Trademark for which registration is sought]</p>  <p>[Color trademark]</p> <p>[Detailed description of trademark] The trademark for which registration is sought consists solely of red (RGB values: 255,0,0).</p>	<p>(Ex. 2) Combination of colors</p> <p>[Trademark for which registration is sought]</p>  <p>[Color trademark]</p> <p>[Detailed description of trademark] The trademark for which registration is sought (hereafter referred to as the “trademark”) consists of a combination of colors. The combined colors are red (RGB: 255,0,0), blue (RGB: 0,0,255), yellow (RGB: 255,255,0), green (RGB: 255,128,0), and the color scheme of the trademark, in order from the top, is 50% red, 25% blue, 15% yellow, 10% green.</p>	<p>(Ex. 3) Specifying the position on product etc.</p> <p>[Trademark for which registration is sought]</p>  <p>[Color trademark]</p> <p>[Detailed description of trademark] The trademark for which registration is sought (hereafter referred to as the “trademark”) is a color trademark consisting of a red color (RGB: 255,0,0) applied on a handle of a knife. Note that the parts of the blade and handle represented by dashed lines are used to illustrate an example use of the trademark in the form of a product and do not constitute elements of the trademark.</p> <p>[Designated goods or designated services and the class of goods or services] [Class 8] [Designated goods (Designated services)] Knife</p>
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4. Sound trademarks

1. Content of [Trademark for which registration is sought]

- A description using (A) musical notation, (B) characters, or a combination thereof, which specifies the sounds for which trademark registration is sought.

(A) If described by musical notation, all of the following must be given:

- Note
- Clef (treble clef etc.)
- Tempo (metronomic indication, tempo marking)
- Time signature (4/4 etc.)
- Linguistic elements (such as lyrics, etc., when included)

(B) If described by words, the following must be given:

- Type of sound

Description using onomatopoeia (for example: the “meow” of a cat, the “clapping” sound of clapping hands, the “whistle” of the wind, the “howling” of the wind, the “clackety-clack” of a machine, the “whine” of a machine).


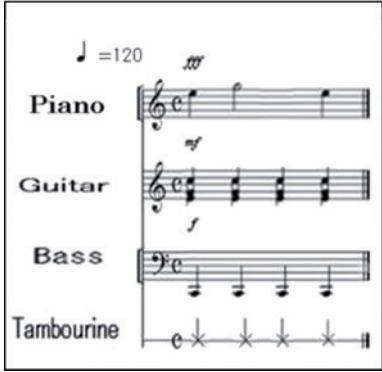
- Other elements necessary to define the sound

Description of the lengths (durations) of the sounds, the number of repetitions of the sounds, the order of the sounds, and changes in the sounds (such as changes in volume, changes in sound dynamics, changes in tempo etc.)

2. Content of [Detailed description of trademark]

Not required but it is necessary to submit a sound file.

3. Approved examples of sound trademarks

<p>(Ex. 1)</p> <p>[Trademark for which registration is sought]</p>  <p>[Sound trademark]</p>	<p>(Ex. 2)</p> <p>[Trademark for which registration is sought]</p>  <p>[Sound trademark]</p>	<p>(Ex. 3)</p> <p>[Trademark for which registration is sought]</p> <div style="border: 1px solid black; padding: 10px; margin: 10px auto; width: 80%;"> <p>The present trademark consists of the “clap” sound of hands clapping repeated twice followed by the “meow” of a cat and lasts for a total of 3 seconds.</p> </div> <p>[Sound trademark]</p>
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5. Position trademarks

1. Content of [Trademark for which registration is sought]

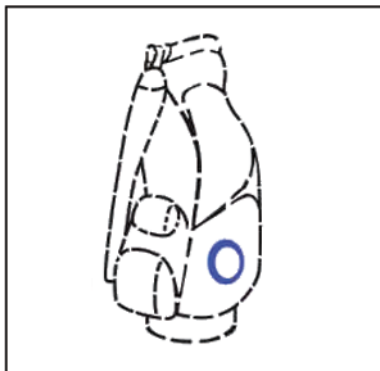
- One or more figures or photos which indicate the position for which a trademark is sought and wherein only the part which corresponds to the said position is shown in a solid line and the other parts are indicated by broken lines, etc.

2. Content of [Detailed description of trademark]

- Concrete, clear explanation of the elements constituting the trademark and the position on the product which bears them (e.g. the name of the site, shape, features etc.)

3. Approved example of a position trademark

[Trademark for which registration is sought]



[Position trademark]

[Detailed description of trademark]

The trademark for which registration is sought (hereafter referred to as the “trademark”) is a position trademark specifying the position of a device applied on a bag for golf clubs. Note that the dashed lines representing the bag for golf clubs are used to illustrate an example use of the trademark in the form of a product and do not constitute elements of the trademark.

[Designated goods or designated services and the class of goods or services]

[Class 28]

[Designated goods (Designated services)] Bag for golf clubs

4. Trademarks relating to international registrations

After its implementation, the revised law will apply to subsequent requests for territorial extension designating Japan. The following is an excerpt from the proposed revision of the “Examination Guidelines for Trademarks”, published by the JPO in February 2015, in relation to international registrations designating Japan.

1. In principle, the determination whether a trademark is considered a “motion trademark”, “hologram trademark”, “color trademark”, “sound trademark” or “position trademark” is made according to (A), (B) or (C):

(A) The determination can be based on the content of the “Indication relating to the nature or kind of marks” in the designation:

- i) If the “Indication relating to the nature or kind of marks” is “mark consisting exclusively of one or several colors”, the trademark is considered a color trademark.
- ii) If the “Indication relating to the nature or kind of marks” is “sound mark” the trademark is considered a sound trademark.

(B) The determination can be based on the content of the “Description of the mark” in the designation:

- i) If the “Description of the mark” contains wording such as “moving”, then the trademark may be considered a motion trademark.
- ii) If the “Description of the mark” contains wording such as “hologram”, then the trademark may be considered a hologram trademark.
- iii) If the “Description of the mark” contains wording such as “positioning of the mark”, “position mark” etc, then the trademark may be considered a position trademark.

(C) If “Indication relating to the nature or kind of marks” is not present and it cannot be determined from the content of the “Description of the mark”, the determination of the trademark type will be based on the trademark shown in the “Trademark for which protection is sought” (i.e. “Mark”) in the designation. For example, if the contents of “Trademark for which registration is sought” is a piece of musical notation but “sound mark” is not stated under “Indication relating to the nature or kind of marks”, then the trademark for which registration is sought is processed as a figurative trademark.

2. The [Detailed description of the trademark] for which registration is sought shall be considered as follows:

- (A) For color trademarks, the contents of “Colors claimed” and “Description of the mark” in the designation are considered as the [Detailed description of the trademark].
- (B) For “sound trademarks”, “motion trademarks”, “hologram trademarks” and “position trademarks”, the contents of “description of the mark” are considered as the [Detailed description of the trademark].

3. As sound files are not attached to international registrations submitted to WIPO when a request for territorial extension designating Japan is made, the JPO will issue an Office Action notifying that a sound file has to be filed.

If you are considering filing an application for a new type of trademark in Japan, please feel free to contact us to discuss your specific needs.

4 Revision of the Patent Term Extension System

1. Patent Term Extension System to Apply to Regenerative Medical Products

In Japan, extensions to the duration of patents relating to agricultural chemicals and pharmaceuticals by up to five years have been recognized.

By the revision of the relevant Cabinet Order and Examination Guidelines, extensions of up to five years are now recognized for patents relating to “regenerative medical products”.

The Patent Term Extension System is defined in Article 67(2) of the Patent Law as follows:

“Where there is a period during which the patented invention is unable to be worked because approvals prescribed by relevant Acts that are intended to ensure the safety, etc. or any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc., of such a disposition is necessary to obtain for the working of the patented invention, the duration of the patent right may be extended, upon the filing of a request for the registration of extension of the duration, by a period not exceeding five years.”

Before the revision, the above “dispositions” were established by Cabinet Order (Patent Law Enforcement Ordinance Article 3) as being registration relating to “agricultural chemicals” based on the provisions of the Agricultural Chemicals Control Law and approval relating to “pharmaceuticals” based on the provisions of the Pharmaceutical Affairs Law.

However, last year’s revision of the Pharmaceutical Affairs Law reorganized the product classification of pharmaceuticals, quasi-drugs, cosmetics and medical equipment, as well as newly classifying “regenerative medical products” (Note that this revision changed the name of Pharmaceutical Affairs Law to the “Pharmaceuticals and Medical Devices, etc. Law” (abbr.)) As a result of consultation, term extensions for patents concerning the newly classified “regenerative medical products” will be recognized. In order to conform to this, the Patent Law Enforcement Ordinance has been revised, adding the approval of “regenerative medical products” to the above dispositions, and in addition, the relevant parts of the Examination Guidelines have also been revised.

Accordingly, following the revision, patents concerning “regenerative medical products” will be subject to patent term extensions, in addition to patents concerning “agricultural chemicals” and “pharmaceuticals”.

2. Regenerative Medical Products

1. Definition of a Regenerative Medical Product

Regenerative medical products are defined as:

- human cells which have been processed (e.g. cultured) and are used with the purpose of reconstruction, repair or formation of the structure or function of the body, or treatment or prevention of disease, or
- something which is used to introduce human cells, for the purposes of gene therapy.

(Article 2(9) of the Pharmaceuticals and Medical Devices, etc. Law)

2. Examples of Regenerative Medical Products

The following are examples of regenerative medical products:

- autologous chondrocytes cultured in *ex vivo* collagen gel
to be transplanted into a cartilage site rendered defective by trauma, with the expectation that function will be restored by the cartilage-like tissue consisting of chondrocyte-collagen gel
- cells containing a cancer antigen peptide and an immune cell activating substance
to be administered into the body of a cancer patient with the expectation of a therapeutic effect

The effective date of both the revised Patent Law Enforcement Ordinance and the revised Examination Guidelines was 25 November 2014, meaning that term extensions for patents concerning regenerative medical products can now also be applied for.