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IN THIS ISSUE

- Supreme Court Decision on Patent Term Extensions
- How “Product-by-Process” Claims are Examined in Japan: Examples of Useful Arguments for Maintaining “Product-by-Process” Claims
- Court Case: Request to Confirm the Absence of the Right to Demand an Injunction in Utility Model Infringement
- Developments in Trademarks and Designs

Supreme Court Decision on Patent Term Extensions

Case No.: Third Petty Bench of the Supreme Court 2014 (Gyo-Hi) 356

Judgment Date: November 17, 2015

Appellant: Commissioner of Japanese Patent Office

Appellee: Genentech, Inc.

The Third Petty Bench of the Japanese Supreme Court handed down the following first-ever decision on an appeal hearing regarding an IP High Court Grand Panel decision. In the case that a marketing approval (“Subject Approval”) is obtained for a later medicine (“Medicine”) that is not substantially identical to an earlier medicine (“Preceding Medicine”) for which marketing approval (“Prior Approval”) had already been obtained, a patent term extension shall be granted based on the Subject Approval. On this basis, the appeal case lodged by the Japanese Patent Office (JPO) was dismissed, thus finalizing the Judgment of the IP High Court which had overturned the JPO’s Appeal Decision that denied a patent term extension requested by the appellee, Genentech, Inc.

Genentech had obtained the Prior Approval for the Preceding Medicine that falls within the scope of the patented invention (“Patent”). Thereafter, Genentech obtained the Subject Approval for a medicine falling within the scope of the same Patent but whose dosage and administration are different from that of the Preceding Medicine. The point at issue was whether the patent term extension should be granted for the medicine for which the Subject Approval was obtained. The Third Petty Bench pointed out that it was not until the Subject Approval was

obtained that the manufacturing and sales of the medicine concerning the Subject Approval were first allowed, thus upholding the Judgment of the IP High Court.

In reaction to this ruling of the Supreme Court, the JPO announced postponement of the commencement of the examination of patent term extension applications including Prior Approvals for medical supplies or agricultural chemicals, and that revision of the Examination Guidelines regarding patent term extensions will be placed under review. Announcement of the Revised Examination Guidelines is scheduled for the spring of 2016.

The Japan Patent Attorneys Association published an English summary of this Judgment as follows.

[English summary edited for clarity by Shiga International Patent Office]

In cases where Prior Approval and Subject Approval have been obtained, if, upon a comparison of the two, the manufacturing and sales of a medicine covered under the Prior Approval include the manufacturing and sales of a medicine covered under the Subject Approval, then the Subject Approval shall not be necessary for implementation of the patented invention with regard to an application for patent term extension. Whether or not Subject Approval is necessary for implementation of a patented invention shall be decided by comparing the Preceding Approval and the Subject Approval. It shall not be decided based on all matters qualifying as matters which specify the patented invention.

Marketing approval of a medicine pursuant to the Drug and Medical Equipment Act allows manufacturing and sales of a medicine identified by each of the examination matters,

specifically, "name, ingredients, quantity, dosage, administration, efficacy, effect, side effects, and other matters relating to the quality, effectiveness and safety" of the medicine. However, given the purpose of the patent term extension system, it is not considered appropriate to compare the approvals based on examination matters that are not directly related to the medicine's substantial identity in light of the type and subject matter of the patented invention for which the patent term extension is at issue. The reason being that such a comparative examination would have the consequence of granting a patent term extension by comparing the approvals on the basis of examination matters that do not interfere with the working of the patented medicine invention.

Therefore, in cases where Subject Approval and Prior Approval have been obtained, when, upon comparison of the approvals in regard to the examination matters directly related to the substantial identity of the medicine in light of the type and subject matter of the patented invention for which a patent term extension is at issue, it has been found that manufacturing and sales of the medicine under the Prior Approval include the manufacturing and sales of the medicine under the Subject Approval, then such shall not be found necessary for implementation of the patented invention with regard to the application for patent term extension.

With regard to the present case, the present invention is related to a composition for cancer treatment, which comprises an effective amount of vascular endothelial growth factor antagonist and is a product invention whose subject matter is an ingredient of the drug. The examination matters that directly relate to the substantial identity of the medicine are: ingredients, quantity, administration, dosage, efficacy, and effects. The Subject Approval allows the manufacturing and sales of the Medicine for a combination of XELOX treatment and bevacizumab treatment for the first time, a combination treatment that was not allowed under the Prior Approval.

Thus, in this case, the manufacturing and sales of the Preceding Medicine were not found to include the manufacturing and sales of the Medicine.

It is concluded that the Judgment of the IP High Court shall be finalized and the appellant's argument cannot be accepted.

How "Product-by-Process" Claims are Examined in Japan: Examples of Useful Arguments for Maintaining "Product-by-Process" Claims

In accordance with two Supreme Court decisions (Case Nos. H24(Ju)-1204 and -2658) handed down on June 5, 2015, the Japanese Patent Office (JPO) changed its practice concerning the examination of "product-by-process (PBP)" claims beginning on July 6, 2015. If the JPO judges that a product claim is defined by a process for manufacturing the product (i.e., the claim is judged to correspond to a PBP claim), the JPO will examine whether or not it would have been impossible to directly specify the product by means of the structure and/or properties thereof, as well as whether or not such a specification would have been impractical

at the time of filing the application. Unless the JPO concludes that this "impossible/impractical" requirement is satisfied by the PBP claim, a reason for rejection concerning "lack of clarity" will be issued.

The revised "Examination Guidelines for Patents and Utility Models" published by the JPO on September 16, 2015, present examples of PBP claims and non-PBP claims as well as examples which satisfy or do not satisfy the "impossible/impractical" requirement. Since the Examination Guidelines do not show any examples of arguments or evidence by which the "impossible/impractical" requirement would be satisfied, the JPO additionally announced five specific examples for the above arguments on November 25, 2015. Below we explain the examples in more detail (the claims in Examples 1 to 5 are regarded as being PBP claims due to the presence of the underlined portion).

Example 1

[Claim 1] An aroma generating device comprising:
 a holder having at least one air vent opening; and
 an aroma source and a heating element disposed in said holder,
 wherein said aroma source includes a molded activated carbon and is heated with said heating element at a temperature in the range from X to Y degrees Celsius, and
 wherein said aroma source is produced by heating said molded activated carbon impregnated with a solution of aromatic ingredient A, at a temperature of less than or equal to the heating temperature of said heating element for Z hours or longer.

Example 2

[Claim 1] A thin film semiconductor device having a structure of ... and comprising an oxide semiconductor film consisting of XXX oxide as an active layer,
 wherein said oxide semiconductor film is formed on a substrate by sputtering, using a metal oxide as a target, wherein the temperature of the surface of the substrate is from X to Y degrees Celsius.

The JPO accepts the following argument by the applicant regarding Examples 1 and 2:

It is impossible to recite, in Claim 1, an element specifying a structure or property which represents a difference from prior art inventions. Furthermore, it was impossible or impractical to analyze and specify the structure or property on the basis of a general measuring method at the time of the filing date. Therefore, the recitation of Claim 1 satisfies the "impossible/impractical" requirement.

Example 3

[Claim 1] An oil-in-water type creamy emulsion composition for food products comprising water, an oil component, emulsifiers, component A, and component B, and having a viscosity of C-D mPa·s,
 wherein emulsifiers X and Y are comprised as said emulsifiers such that the weight ratio of emulsifiers X/Y is 10-20/30-40, and
 wherein said emulsion composition is obtained by mixing and stirring the emulsifiers, the component A, and the component B so as to prepare an oil phase, adding the prepared oil phase to a water phase, and emulsifying them.

The JPO accepts the following argument by the applicant regarding Example 3:

Depending on various specific embodiments of the claimed manufacturing method, the structure or property of the

product manufactured by the method greatly varies. Furthermore, it is not possible to comprehensively represent the variety of structures or properties of the resulting composition in a claim. Therefore, the recitation of Claim 1 satisfies the “impossible/impractical” requirement.

Example 4

[Claim 1] A flavor improving agent prepared by the successive steps of:

obtaining a concentrated solution by heating and concentrating a sugar cane juice at a temperature of 120-130 degrees Celsius until an indicator of a sugar refractometer becomes 70-80 degrees on a Brix scale; and

collecting a distillation by recovering and cooling vapor obtained through the distillation of said concentrated solution at a temperature of 120-130 degrees Celsius.

The JPO accepts the following argument by the applicant regarding Example 4:

The flavor improving agent is derived from a natural product and it is impossible or impractical to directly specify the agent by means of a structure (composition) or property thereof. Therefore, the recitation of Claim 1 satisfies the “impossible/impractical” requirement.

Example 5

[Claim 1] A polymerized composition prepared by the steps of: preliminarily reacting a compound having three or more mercapto groups per molecule and a compound having two or more isocyanate groups per molecule for 5 to 10 minutes at a temperature of 40-50 degrees Celsius; and then reacting a reaction solution containing an oligomer obtained by said preliminary reaction, a compound having two mercapto groups per molecule and

The JPO accepts the following argument by the applicant regarding Example 5:

The obtained product prepared by using the process recited in Claim 1 is a mixture of polymers having very complicated structures which are too complicated to be specified by using a general chemical formula. Furthermore, it was impossible or impractical to directly specify the polymers by means of the properties thereof because the properties vary depending on the compositions of monomers which are specifically used and the reaction conditions that are specifically employed. Therefore, the recitation of Claim 1 satisfies the “impossible/impractical” requirement.

If you would like more detailed information, please refer to the following JPO website:

https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/pdf/product_process_C151125_e/pbpc_sankourei_e.pdf

Court Case: Request to Confirm the Absence of the Right to Demand an Injunction in Utility Model Infringement

Case No.: Osaka District Court 2014 (Wa)-5064

Judgment Date: March 26, 2015

Japanese Utility Model Registration Number: 3158266 (Stable Dais Chair)

Japanese Utility Model Law stipulates that a utility model shall be registered without substantive examination. This law also establishes a system for providing Utility Model Technical Opinion Reports (hereinafter, referred to as “UMTORs”) prepared by a JPO Examiner and stipulates that a utility model right owner cannot enforce the right against an infringer unless a warning is given containing a favorable UMTOR regarding the registered utility model (Japanese Utility Model Law, Article 29^{bis}).

With regard to this court case, the defendant (utility model right owner) had notified the plaintiff that the plaintiff’s product allegedly infringed the defendant’s utility model right but the defendant did not present an UMTOR to the plaintiff. In response, the plaintiff claimed that the defendant’s utility model right was invalid and filed a request to cease such an act as well as compensation for damages since the plaintiff regarded the defendant’s action as a violation of the Japanese Unfair Competition Prevention Law. The Osaka District Court accepted the plaintiff’s claim.

Overview of the Case

The right owner (defendant) of the utility model in question which is directed to a “stable dais chair” notified the plaintiff and relevant distributors who manufacture and sell dais chairs that the defendant regards the plaintiff’s product as infringing the utility model right (warning letter and notice). However, the defendant did not present the plaintiff with the UMTOR which found the utility model to lack inventive step.

The plaintiff claimed that this utility model right was invalid and filed a request to confirm the absence of the right to demand an injunction in utility model infringement. At the same time, the plaintiff sought compensation for damages since the plaintiff regarded the defendant’s act of notifying the distributors as a violation of the Japanese Unfair Competition Prevention Law.

Points in Dispute and Grounds for Judgment

1) Request to confirm the absence of the right to demand an injunction

Despite the JPO’s UMTOR which found that there existed grounds for invalidating the utility model right, the defendant notified the plaintiff and relevant distributors that the plaintiff’s product allegedly infringed the defendant’s utility model right. The defendant had also requested an injunction against the plaintiff to cease manufacturing and sales of the plaintiff’s product. The Court accepted the plaintiff’s request to confirm the absence of the right to demand an injunction and the request for compensation.

2) Defendant’s violation of the Japanese Unfair Competition Prevention Law

The defendant had sent a notice to the relevant distributors without presenting the UMTOR regarding this utility model right. In other words, the defendant sent the notice to the distributors under the pretense that the utility model right was valid. It must be said that such an action by the defendant should be regarded as making a false allegation that undermines the business credibility of competitors under the Japanese Unfair Competition Prevention Law.

The defendant claimed that this utility model right is not invalid and that their act of indicating their recognition of the facts and of seeking confirmation of the plaintiff’s response is not illegal. The Court considered that the defendant would likely act in the same way in the future, and therefore decided that the defendant should cease the above action.

3) Request for Compensation

The Court concluded that the defendant's actions of sending a warning letter and seeking an injunction against the plaintiff and relevant distributors without presenting the UMTOR are regarded as an enforcement of the utility model right without presenting the UMTOR. In addition, the defendant's act of indicating that the plaintiff's product allegedly infringes the utility model right by sending a notice to the distributors is regarded as giving a warning without presenting the UMTOR. Although the

defendant recognized that there was a strong possibility that the utility model right would be invalidated and the enforcement of the right would thereby be denied, the defendant terminated transactions involving the plaintiff's product. These were judged to be deliberate actions which are counter to the Japanese Unfair Competition Prevention Law and are highly illegal. Accordingly, the Court judged that the defendant must pay compensation as well as attorney fees to the plaintiff.

Developments in Trademarks and Designs

Registration Examples of Japanese Trademarks since the Trademark Law Revision of April 2015

Forty-three non-traditional trademarks, such as sounds, motions, positions, etc., have been newly registered

Due to the revision in April 2015, it is now possible to apply for trademarks for "sounds", "colors", and other distinguishing features which are frequently used to represent a company's products or brand image. The JPO announced the breakdown of 43 registrations of such new types of trademarks. In 2014, the Trademark Law was revised for the purpose of supporting diversity of companies' brand strategies. It is now possible to apply for non-traditional trademarks, such as motions, colors, sounds, holograms, and positions in addition to traditional character, graphic, and three-dimensional trademarks. This revision has attracted a great deal of interest from companies, and a total of 1,039 applications were filed from April 1, 2015 to October 23, 2015.

On the other hand, there have been no registrations of "color" trademarks for which the greatest number of applications have been filed, due to the difficulty of proving distinctiveness. Office Actions requesting documents to prove acquired distinctiveness are now being issued, and the JPO will carefully examine the distinctiveness of the applied-for "color" trademarks on a case-by-case basis.

	Sound	Motion	Position	Hologram	Color	Total
Number of registrations	21	16	5	1	0	43
Number of applications on April 1, 2015	151	32	103	3	192	481
Total number of applications until October 23, 2015	321	70	214	11	423	1,039

Graphic Image Search for Designs

On October 1, 2015, the Japanese Patent Office (JPO) launched "Graphic Image Park", a graphic image search service for designs. The "Graphic Image Park" can be used to search for graphic image designs registered in Japan thus enabling users to check whether the use of their designs would potentially infringe design rights of third parties.

This service employs image matching technology and can be used any time free of charge via the Internet. Various graphic image designs registered in Japan can be checked, and the designs found in the search are shown in the order of similarity which is automatically judged based on conditions such as shapes or colors specified by users.

Website: <http://www.graphic-image.inpit.go.jp>

JPO Starts New Trademark Search Service – FOPISER

The JPO has also launched a new search service for trademarks named FOPISER, the Foreign Patent Information Service.

Since August 2015, FOPISER allows individuals to search for Russian, Taiwanese, and Australian patent/utility model publications and Russian and Taiwanese design publications. In addition, access to Russian, Taiwanese, and OHIM trademark information became available on September 30, 2015.

Website: <https://www.foreignsearch.jpo.go.jp>

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