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Life Cycle Management of Drugs and Patent System in Japan (2)

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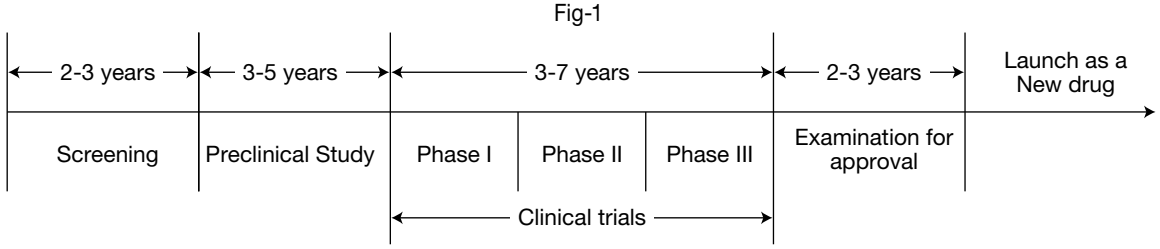
5.1 Life cycle of drugs and pharmaceutical inventions

Research of a drug targeted on a specific disease usually commences by establishment of a screening system. Thereafter, a leading compound is selected and various derivatives thereof are subjected to screening for optimization. In common practice, a compound having good pharmacological activities is obtained to proceed with the filing of a patent application covering them. In most cases, it is expected to take 10 to 18 years from the commencement of research of a drug to the marketing launch after the approval for manufacturing is obtained, including the period of the above-described screening (Fig-1).

For example, if the marketing of a drug is launched 15 years after an initial patent application, only a period of five years remains during which a drug can be marketed exclusively based on the patent right. It is, therefore, difficult to secure sufficient profit and resources for research and development for continuing the development

Fig-1



of desired new drugs. Under the Japanese patent law, an extension of the patent term up to five (5) years can be obtained as a countermeasure.

On the other hand, there is a case where a compound including a certain enantiomer, a pharmaceutically acceptable salt and a solvate such as a hydrate, which has superior properties as a pharmaceutical, is found in the scope of the claims of an initial application during the development period after the initial application. A separate patent application should be filed for such a compound as a selective invention. If the invention has high patentability, a patent right may be granted even where it is filed after publication of the initial application. Further, a patent right having a late filing date also has a late patent expiration date, which may contribute to a substantial extension of the term during which a drug can be exclusively marketed. Similarly, evaluation should be made for possible patent applications for respective inventions covering a new medicinal use of a development compound, a process for preparation, a crystal form, a combination use with other drugs, and a special formulation. Under the Japanese patent practice, each patent covering a drug for which approval for manufacturing is newly obtained may be subject to registration of a patent term extension of up to five (5) years (refer to YUASA and HARA IP NEWS Vol.25).

It is difficult to obtain patents for these pharmaceutical applications because the number of relevant prior art documents increases as the filing date is delayed. It is, therefore, preferable to file an application before issuance of the publication of the first application in view of patentability of the later application.

5.2 Medicinal use invention

There is a case where a new indication, a specific administration method and a remarkable effect resulting from a combination with other drugs may be found in clinical trials of a development drug. A patent application may be filed based on an invention resulting from the above findings as a medicinal use invention. According to the Examination Guidelines for Patent and Utility Model in Japan issued by the Japanese Patent Office (referred to as "Examination Guideline" hereinafter), there is provided a paragraph for medicinal inventions as examination guidelines for specific technical fields, an English translation of which is available at the website of the JPO: (http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/1312-002_e.htm ; Part IV, Chapter 3: Medicinal Invention). The Japanese patent practice related to medicinal use inventions will be described below.

a. Claim drafting for medicinal use invention

The Japanese Patent Office does not grant any patent for an invention regarding "a method of surgical operation for humans, treatment and diagnosis" because it is regarded as an invention of medical activities which are not industrially applicable (the principal clause of Article 29, Paragraph 1 of the Japanese patent law), and this patent practice has been supported by judicial precedent (Case of claiming the revocation of appeal decision No. 65, Administration Ke, 2000). On the other hand, "invention of product" such as a pharmaceutical composition, which is to be administered to humans, is recognized as an industrially applicable invention. Medicinal inventions specified by a combination of two or more drugs or a method of treatment such as a dose interval and dosage are also handled similarly, as long as they are "inventions of products." For example, the following claim drafted in a format of "method for treatment" which is admissible under U.S. patent practice may be handled as an industrially applicable invention if it is rewritten as a pharmaceutical composition (invention of product).

[Medical treatment claim]

A method for treatment of hepatitis C in a patient having α-type genotype, comprising administering compound A to the patient at an initial dose of 5.0mg/kg to 10.0mg/kg, followed by a dose of 0.3mg/kg to 0.5mg/kg on alternate days.

[Pharmaceutical composition claim]

A pharmaceutical composition comprising compound A as an active ingredient for treatment of hepatitis C in a patient having α-type genotype, which is administered to provide the patient with compound A at an initial dose of 5.0mg/kg to

10.0mg/kg, followed by a dose of 0.3mg/kg to 0.5mg/kg on alternate days.

In addition to such a pharmaceutical composition claim, a claim reciting an agent or a kit as a subject matter is generally accepted as a format of drafting a medicinal invention. One example is shown below.

An agent for treating or preventing disease Z, comprising compound X as an active ingredient.

A kit for treating disease Z, comprising compound X in a dosage form for oral administration; and compound Y in a dosage form for injection.

On the other hand, regarding a claim drafted in a format of "compound for a specific use," the Examination Guidelines in Japan state that the phrase "for a specific use" shall not be interpreted as definition of an invention (Chapter 2, Section 1. 5. 2 (2)). For example, regarding the following claim in which a compound X is a known compound: "A compound X for use as a medicament in the treatment of disease Z", under the current examination practice in Europe, an invention described in the claim is interpreted as a second medicinal use invention of a known compound. However, under Japanese examination practice, it is interpreted as a compound without restriction of use and consequently determined to be without novelty.

A claim intended for "use of compounds in the preparation of medicament" (a so-called Swiss-type claim; "e.g. A use of compound X in preparation of a medicament for treating disease Z") is interpreted as "an invention of use method" and as "an industrially applicable invention" under Japanese patent practice. Many applications including a Swiss-type claim are patented. On the other hand, some examiners in Japan have stated that a claim drafted in the above format is not sufficiently clear. Further, so far there has been found no example of any actual enforcement of a Swiss-type claim. Therefore, it is considered that a patent application covering the second medicinal use should include at least one claim reciting "invention of product" such as a pharmaceutical composition, in view of stability of patent right.

b. Disclosure of pharmacological test results in specification

As an enablement requirement of a medicinal use invention under the Japanese patent practice (Article 36, Paragraph 4, item No.1 of the Japanese patent law), it is required to disclose, in an original specification, pharmacological test results which support a medicinal use as one or more representative examples (Examination Guidelines, Chapter 3, Section 1. 2. 1). According to the Examination Guidelines, as pharmacological test results, the specification shall disclose the following matters: (i) a specific compound used in the test, (ii) full explanation of a pharmacological test system used in the test, (iii) the test results specifically shown in terms of values or the like, and (iv) the relationship clarified between a medicinal use to be claimed and the pharmacological test system used. The Examination Guidelines also state that when the subject specification fails to disclose any pharmacological test results, rejection for failure to meet enablement requirement will not be overcome even if pharmacological test results are submitted after application. The Japanese Patent Office has applied the Examination Guidelines strictly to the enablement requirement, thereby making the requirement more strict than that of the US and EP.

[Judicial precedent 1]

The case of claiming the revocation of appeal decision No. 10312, Administration Ke, 2005 (plaintiff: Astellas Pharma Inc., defendant: Commissioner of the Japanese Patent Office)

The claim in Japanese Patent Application No. H08-532341 (corresponding to PCT application: WO96/33715) recites as follows:

An agent for preventing and/or treating dialysis-induced hypotension and/or hypotension after dialysis, which comprises 1-[3-(2-phenyl-pyrazolo[1,5-a]pyridin-3-yl) acryloyl]-2-(carboxymethyl) piperidine or a salt thereof as an active ingredient.

An appeal decision was issued by the JPO, rejecting the application on the grounds that the subject specification did not meet the enablement requirement. In the case for seeking revocation of the decision, the judge supports the original decision and states as follows:

"The subject specification describes, in addition to the compound recited in the claim, that the com-

pound is an active ingredient of a therapeutic agent for the disease recited in the claim. Further the specification discloses to some extent an effective amount, an administration route and formulation of the therapeutic agent. However, it is clear that there is neither pharmacological data supporting the usability of the compound as the therapeutic agent for treating the disease recited in the claims nor any description equivalent to such pharmacological data. The subject specification merely describes, to some extent, an effective amount, the administration route and formulation of the therapeutic agent. However, such descriptions are not sufficient for a person skilled in the art to understand whether or not the agent is actually effective in the use claimed. This is also the same as the judgment made for the original appeal decision."

Incidentally, the EP application and the US application corresponding to the application concerned have each been granted a patent for broader claims (refer to EP 0823254B1 and US 6232324B).

Further, where there is no description of pharmacological test results in the specification, rejection for failure to meet support requirement (Article 36, Paragraph 6, item No.1 of the Japanese patent law) may also be notified. Still further, where an assertion is made for the inventive step of a medical use invention (Article 29, Paragraph 2 of the Japanese patent law), significant effects provided by the subject invention are often asserted on the basis of pharmacological test results disclosed in the specification. Under the current Japanese practice, it is preferable that the maximum possible pharmacological test results are disclosed in the initial specification.

[Judicial precedent 2]

The case of claiming the revocation of trial decision No. 10459, Administration Ke, 2005 (participant: Zepharma Inc., defendant: Commissioner of the Japanese Patent Office)

Regarding Japanese Patent No. 3264301, the patentee demanded a trial for correction to introduce the following amended claim:

A pharmaceutical formulation for nasal drops, which comprises sodium cromoglycate (1%), chlorpheniramine maleate (0.25%) and naphazoline hydrochloride (0.025%).

However, the trial decision was issued by the Japanese Patent Office to dismiss the demand for correction on the grounds that the invention recited in the amended claim lacks inventive step. In the lawsuit for revocation of the trial decision, the patentee asserted the significant effects of the invention (peak effects) in addition to difficulty in reaching the combination of the ingredients. In this regard, this judgment points out that the subject specification includes clinical test results of patients with allergic rhinitis but does not include a specific protocol of the clinical test, specific data supporting individual improvements in various symptoms of allergic rhinitis and the specificity of the claimed concentration of the ingredients; and concludes that "neither the peak effect provided by the invention of the amended claim nor remarkable improvements in nine symptoms asserted by the participant cannot be confirmed specifically by referring to a description in the subject specification." Consequently, the court dismissed the demand of the participant.

[Judicial precedent 3]

The case of claiming the revocation of appeal decision No. 10389, Administration Ke, 2005 (plaintiff: Kowa Company Ltd., defendant: Commissioner of the Japanese Patent Office)

The Japanese Patent Office made an appeal decision rejecting Japanese Patent Application No. H10-341452 on the ground of lack of inventive step. The application claims the following invention:

An antipyretic antiphlogistic analgetic agent comprising ethenzamide and tranexamic acid.

In the case for seeking revocation of the appeal decision, the judge stated, by referring to a citation, that "at the subject filing date, a use of an antipyretic antiphlogistic analgetic agent in combination with tranexamic acid was considered as providing a synergistic effect and as a combination for improving a therapeutic effect. To assert a remarkably significant effect in judging the patentability of the subject

invention, it is not sufficient to indicate simply a synergistic effect. However, it is necessary to indicate an inherent effect, which cannot be obtained in combination with a salicylate-related anti-inflammatory agent that is an antipyretic antiphlogistic analgetic agent other than ethenzamide", and recognized that "the subject specification does not include grounds necessary for assessing the claimed combination, and as a result, no remarkably significant effect can be recognized in the subject invention."

Further, the plaintiff submitted additional test data showing that no enhanced antiphlogistic effect is found in combination of tranexamic acid with other antipyretic antiphlogistic analgetic agents such as acetaminophen, and argued that the enhanced antiphlogistic effect obtained only in combination of ethenzamide with tranexamic acid should be recognized as a remarkably significant effect. In response to this argument, the judge stated that "the subject specification does not include a description suggesting that the use of ethenzamide provides such a significant effect as compared with the use of a salicylate-related antiphlogistic agent other than ethenzamide and, therefore, the assertion of the plaintiff is not based on the description in the subject specification", and consequently supported the appeal decision originally made by the JPO.

5.3 Selective invention relating to pharmaceuticals

There is a case where after an application is filed for covering the resulting compounds of screening in a first phase of drug development, favorable pharmacological properties are found in a compound which falls within a scope of the claims but is not specifically disclosed in the specification of the application. There is also a case where favorable properties are found in a novel crystal form of a development candidate compound. Such a compound and a crystal form having excellent properties may be granted a patent as a selective invention.

Under the pharmaceutical legislation of the EU, even where a formulation contains a derivative (salt, ester, isomer and the like different from an active ingredient of an original drug) of an active ingredient of the original drug, the derivative is considered as the same active ingredient as long as no significant difference is found in safety and efficacy. Therefore, the formulation is approved as a generic drug.

On the other hand, for a generic drug to be granted approval for manufacturing under Japanese practice, it must contain the same active ingredient as that of an original drug. For example, if active ingredients of an approved original drug are a specific salt, an ester and a hydrate, the generic drug is also required to contain a salt, an ester and a hydrate, which are chemically identical to those of the original drug. Therefore, in Japan, there is a case where a patent right on a specific salt and a hydrate of an active compound may play an important role in life cycle management of a drug in which they are contained as an active ingredient.

However, where an application covering a selective invention is filed after publication of related applications, it is usually required during examination to indicate a remarkably excellent effect of the subject invention, as compared with the inventions disclosed in the related prior applications. This point must be taken into account in preparing the specification.

Further, there are cases that a patent has been granted to a specific optical isomer, even if a racemic form is publicly known. On the other hand, there is a judicial precedent stating that each of the optical isomers is substantially disclosed due to the fact that a racemic form has been disclosed (Case of claiming the revocation of appeal decision No. 8, Administration Ke, Tokyo High Court, 1991). Where a patent application is filed for a selective invention relating to a specific optical isomer, we consider that it is preferable to include a medicinal use claim in the application, for example: "A pharmaceutical composition for treating disease X, which comprises R-enantiomer of compound X at enantiomeric excess of 80% or more.

[Judicial precedent 4]

The case of claiming the revocation of appeal decision No. 62, Administration Ke, 2003 (plaintiff: Aventis Pharma Societe Anoyme, defendant: Commissioner of the Japanese Patent Office)

This is a case for seeking revocation of an appeal decision by the JPO rejecting Japanese Patent Ap-

plication No. H04-504006 (corresponding to WO 92/12980), which claims the following invention:

A pharmaceutical composition for improving quality and/or length of sleep, which comprises a dextrorotatory isomer of 6-(5-chloro-2-pyridyl)-5-[(4-methyl-1-piperadinyl)-carbonyloxy]-7-oxo-6,7-dihydro-5H-pyrolo[3,4-b]pyrazine or a pharmaceutically acceptable salt thereof in combination with one or more pharmaceutically acceptable diluents or adjuvants.

In the judgment, the judge stated as follows: "the plaintiff has asserted a remarkably significant pharmacological effect of the subject invention on the ground that one of the optical isomers (dextrorotatory isomer) claimed as the subject invention has an activity more than twice higher than that of a racemic form, and such a high activity of the subject invention is beyond expectation of a person skilled in the art. However, such a value of activity of twice corresponds to a value obtained in a case that one of the optical isomers is active, while the other is inactive (no activity). It has been previously stated that a chemical compound having optical isomers is diverse in exhibiting pharmacological activities. Exhibit B-2 points out that there is a case where one of the optical isomers may act as an antagonist on pharmacological activities of the other isomer, and Exhibit B-1 also describes that "one of the isomers not only fails in exhibiting any activity but also gives competitive inhibition to an effective enantiomer, thus resulting in a drastic decrease in bioactivity of the racemic body to 1/2 or less as compared with an active enantiomer, and this situation has often been experienced in the research and development of pharmaceuticals," suggesting a possibility that one of the optical isomers may have an activity more than twice higher than that of the racemic form. With these findings taken into account, such an effect asserted by the plaintiff for the subject invention that a dextrorotatory isomer of zopiclone has a sleeping activity more than twice higher than that of the racemic form should be recognized as one embodiment of differences in pharmacological activity among optical isomers, and therefore the effect cannot be considered as a remarkable effect beyond expectation of a person skilled in the art". Consequently the judge denied an inventive step of the subject invention.

[Judicial precedent 5]

The case of claiming the revocation of appeal decision No. 10271, Administration Ke, 2006 (plaintiff: Merck & Company Incorporated, defendant: Commissioner of the Japanese Patent Office)

This is a case for seeking revocation of an appeal decision by the JPO, rejecting the Japanese Patent Application No. H11-507368 (corresponding to WO99/01444), which claims the following invention:

A polymorphic form of the compound 2-(R)-(1-(R)-3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo) methylmorpholine designated Form I, essentially characterized by an X-ray powder diffraction pattern with key reflections as 12.0, 15.3, 16.6, 17.0, 17.6, 19.4, 20.0, 21.9, 23.6, 23.8, and 24.8° (2 theta).

The plaintiff estimates, based on the difference in solubility between these crystals, that the crystal of the subject invention (I-type crystal) is more stable than a known crystal (II-type crystal) by 0.2Kcal/mol, and asserts that "since there is found the above difference in stability, it is clear for a person skilled in the art that a significant improvement is obtained in various respects such as the homogeneity of a pharmaceutical formulation, the bioavailability and the stability." In response to the assertion, the judge stated that "there is not sufficient evidence indicating that the difference in the free energy will directly provide practical superiority of the I-type crystal in stability (e.g. stability in storage at room temperature), compared with the II-type crystal. Therefore, the thermodynamic stability of the subject invention is not approved as a significant effect which is beyond expectation," and denied an inventive step of the subject invention.

6. Lawsuit for Injunction against Generic Drugs

6.1 Procedures of application for approval of generic drugs and patents

An application for approval of generic drugs must be submitted to the regulatory authority (Ministry of Health, Labor and Welfare) after termination of the re-examination period of an original drug (refer to YUASA and HARA IP NEWS Vol.25), and the authority confirms during examination that there is no substance patent covering an active ingredient of the original drug. Where an application for approval of a first generic drug is filed, it is required to attach information on a substance patent (and use patent) of an active ingredient of the original drug. On the other hand, an original drug company can submit in advance information on patents for their original drugs to the regulatory authority. The submitted information shall not be disclosed to any third party. The regulatory authority examines the patents on the basis of the submitted information. The examination is made mainly for a substance patent, while it is made for a use patent only when a clear judgment can be made.

In a judicial decision made by the Supreme Court in 1999 (the judicial decision made at the second petty bench of the Supreme Court on April 16, 1999), an act of conducting various tests necessary for an application for approval for a generic drug during the term of a patent right held by an original drug company is recognized to fall within "implementation of a patented invention for test or research" as stipulated in Article 69, Paragraph 1 of the Japanese patent law, and the judgment stipulates that no effect of patent right is enforceable.

6.2 Case of lawsuit for injunction against generic drugs

When there is a patent which will pose problems in examining approval for a generic drug, a manufacturer of generic drugs has to invalidate the patent, by demanding a invalidation trial before the Japanese Patent Office prior to the examination of approval. On the other hand, the regulatory authority will not evaluate all patent rights held by a manufacturer of original drugs. Thus, a case may arise where a generic drug may be approved despite the fact that the generic drug infringes a patent right owned by an original drug company. For the original drug company one course of action would be to file a lawsuit seeking injunction against marketing of the approved generic drugs.

[Judicial precedent 6]

The case of seeking the injunction against patent right infringement No. 19162, Wa, 2005 (plaintiff: Astellas Pharma Inc., defendant: Taiyo Pharmaceutical Co., Ltd.)

Injunction against the manufacture and marketing of a product of the defendant was demanded on the ground of infringement of the patent right of the plaintiff (Japanese Patent No. 1943842, Japanese Patent Application No. S63-202527). The product of the defendant is a generic drug manufactured and marketed by the defendant, which contains cefdinir as an active ingredient. Claim 1 of the subject patent covering a crystal of cefdinir reads as follows:

A crystal of 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamide]-3-vinyl-3-cephem-4-carboxylic acid (syn- isomer), characterized by an X-ray powder diffraction pattern with peaks near the following diffraction angles: 14.7, 17.8, 21.5, 22.0, 23.4, 24.5 and 28.1°. (Hereinafter, the crystal of the subject invention is referred to as "A-type crystal").

The plaintiff obtained the pharmaceutical formulation of the defendant, conducted X-ray powder diffraction, confirmed that the active ingredient of the pharmaceutical formulation of the defendant exhibited peaks at diffraction angles recited in claim 1, and submitted the results as evidence.

The defendant asserted that the crystal disclosed in Example 16 of the prior art document (Japanese Patent Public Disclosure No. S59-89689) is the A-type crystal, by showing experimental results that an X-ray powder diffraction pattern of the crystal obtained by their follow-up experiments in accordance with the method described in the document coincides with that of the A-type crystal. Further the defendant asserted that the subject patent lacks novelty and should be invalidated.

The plaintiff asserted that since a solid obtained in Example 16 of the prior art document is significantly different in IR spectrum indicated in the document from that of the claimed crystal, the solid is not the crystal of the patented invention. Further, the plaintiff pointed out that in the follow-up experiments conducted by the defendant, the deposit of a target substance occurred in a step of concentrating a solution prior to a step of crystallization by pH adjustment, and asserted that such procedures are not reasonable and the experiment conducted by the defendant does not exactly correspond to the method disclosed in Example 16. In addition, the plaintiff conducted separately their experiments in line with Example 16 and submitted results of a follow-up experiment indicating that no A-type crystal is obtained.

First, the judge admitted that the pharmaceutical formulation of the defendant belongs to the scope of the subject patent.

Regarding the defendant's assertion of invalidation of the patent, first of all, the judge stated that the solid described in the prior art document is not the A-type crystal, since its IR spectrum is different.

Further, the judge indicated criteria for the decision:

"an invention disclosed in a publication distributed in Japan or abroad or an invention made publicly available through electric communication lines before a patent application is not patented (Article 29, Paragraph 1, Item No. 3 of the Japanese patent law,). However, 'the invention disclosed in a publication' includes not only an invention, the content of which is described in the publication but also an invention which can be induced from matters described in the publication, in light of common technical knowledge at the time of filing of the application. Therefore, an invention, the content (technical idea) of which could be easily implemented by a person who has ordinary knowledge in a technical field to which an invention belongs (a person skilled in the art) on the basis of the content described in the publication and common technical knowledge at the time of filing of the application, cannot be patented."

Regarding the result of the follow-up experiments submitted by the defendant, the judge stated that such an experimental step that a target compound starts to deposit in mid-process of concentration cannot be regarded as a follow-up experiment conducted exactly in line with the description in Example 16 of the cited publication, and further stated "it is not considered that a method of manufacturing the A-type crystal of cefdinir is disclosed to such an extent that a person skilled in the art could easily implement the method." and recognized that no reason is found for the invalidation of the patent concerned asserted by the defendant.

In conclusion, the court ruled in favor of an injunction against the manufacture and marketing of the product of the defendant. The conclusion of this judgment was also backed by the appeal court (case of appeal for seeking the injunction against patent right infringement No. 10034, Ne, 2007).

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Patent Attorney of the Patent Division
Takumi Terachi (Mr.);
Patent Attorney of the Patent Division

Seashell Chocolate Bar Determined as Inherently Distinctive as 3D Trademark:

Plaintiff: Chocolaterie Guylian N.V.

Defendant: Commissioner, The Japan Patent Office

Case Number: (Gyo-Ke) 10293/2007, IP High Court, June 30, 2008

1. Summary

A month after the decision on the Coca-Cola Contour bottle case recognizing acquired secondary meaning[*1], Nobuyoshi Tanaka, the presiding judge of the Fourth Bench of the Intellectual Property High Court, issued an interesting decision involving a three-dimensional trademark consisting of the GUYLIAN Seashell chocolate bar. In contrast to the Coke decision, which denied inherent distinctiveness of the bottle shape, the Court ruled that the three-dimensional configuration of the chocolate bar is sufficiently distinct, unique and novel to warrant registration.

2. Case History

The plaintiff Chocolaterie Guylian N.V. filed a three-dimensional configuration of what is called the Seashell Chocolate bar, as shown below, for chocolate and pralines in class 30 via the Madrid Protocol route (International Reg. No. 803,104).

The Appeal Board of the JPO sustained the examiner's refusal and dismissed the applicant's appeal on the grounds that the configuration of the chocolate bar falls under Article 3.1(iii)[*2] of the Trademark Act and further that it had not acquired secondary meaning under Article 3.2.

In an effort to reverse the refusal, the applicant filed an appeal with the IP High Court.

3. Analysis by the IP High Court

3.1 The Meaning of Article 3.1(iii)

The IP High Court began its analysis of the case by reciting, as applicable precedent, the 1979 decision of the Third Petty Bench of the Supreme Court, which defined the meaning of Article 3.1(iii) of the Trademark Act. From the reading of this definition, the IP court understood the "inherently unregistrable trademarks" provided for in this provision as comprising and limited to two types of unregistrable marks, namely:

(Type 1 - marks not suitable for monopoly)

Marks that are not suitable for a particular party to enjoy an exclusive right to use because any party may need to use them in trading as an indication appropriate for the goods concerned; and

(Type 2 - marks lacking the ability to distinguish)

Marks that are generally used and, in most cases, cannot function to identify a source due to their lack of distinctiveness.

3.2 Composition of the Plaintiff's Seashell Bar

In light of the said precedent, the High Court felt that the very point of issue in this case is whether the configuration of the chocolate bar is tantamount to being one of those defined as Type 1 or Type 2 marks as above. The Court then considered the composition of the three-dimensional mark filed by Guylian and determined that the Seashell chocolate bar is constituted by the following three elements in combination:

(a) The rectangular chocolate bar is divided by straight grooves into four square blocks in line;

(b) On each block, there is an object representing a prawn, a fan-shaped shell, a horse-fish with a curly tail (Hippocampus) or a blue mussel, in this order; and
(c) Each shellfish is colored in a marble-like pattern.

3.3 Whether the Seashell Bar Configuration is unsuitable to be granted a monopoly?

In an attempt to demonstrate that consumers would readily assume the plaintiff's chocolate bar as being common, or a mere variation of product configuration, the defendant (JPO) filed evidence demonstrating the fact that several other producers had sold chocolates as follows:

(i) In the form of a plain bar or rectangular plate with straight grooves dividing the bar to form several blocks in line (common chocolate bar type);
(ii) In the shape of a leaf, nut, prawn, seashell, horse-fish, etc. (common 3D type);
(iii) Composed of circular, oval or rectangular base with a piece(s) in the shape of a leaf, fruit mounted thereon (common decorated 3D type); and
(iv) Composed of a bar having crossing grooves to form square blocks on its surface with a hat-shaped 3D piece mounted on each block.

Nonetheless, the Court recognized the difference from these, and found that:

> This three-dimensional shape of Guylian chocolate bar is *distinct and unique* in the sense that no evidence presented by the parties shows the existence of any other similar shapes or configurations in terms of the choice of the four species of shellfish and the three-dimensionally modeled designs thereof, the sequential arrangement thereof, and also the colored marble-like pattern; and also that
>
> With the intention of adopting it as the configuration or shape of their chocolate bar, the plaintiff (applicant) created this chocolate bar design on the basis of the shellfish designs they have been using since 1958 when they established the company.

The Court thus held that the Seashell Bar configuration does not amount to a "Type 1 mark" above.

3.4 Whether the Seashell Bar lacks the ability to distinguish?

Next, the Court considered whether the chocolate bar should be regarded as a mark of Type 2 above. Based on the same recognition as to the configuration of the chocolate bar as being formed by the combined elements (a) – (c), the Court noted that no similar products can be found amongst the evidence submitted by the parties and determined that the chocolate bar of the combined elements (a) – (c) is *novel*. It further opined as follows:

> "The overall impression given by the combined factors (a) – (c) is so distinct as compared with others that general consumers may use it as an identifier when they make a decision as to which chocolate to buy or not to buy on the next occasion of purchase. The methodological way of arranging shellfish, etc. as used in the plaintiff's chocolate bar would, as the defendant argues, not be original or novel. However, the configuration of the chocolate bar with the actual and material combination of the said elements defined as above is found to be novel, distinct and unique, and it is assumed that this level of distinctiveness would enable the general public, having eaten the Seashell Bar, to distinguish it from others both by the taste they had experienced, and by its novel shape."

The Court thus held that the present trademark composed of a Seashell Bar configuration is not a "Type 2 mark" that is commonly used and unable to function as identifying a source due to lack of distinctiveness.

In response to the defendant's argument that only unusual shapes unrelated to the function or aesthetic features of a product have inherent distinctiveness, the Court added that:

(i) As the inherent value of products indeed resides with their functions and aesthetic features, it is

hardly possible to imagine the actual existence of such a shape or configuration of product that it could meet the criteria argued by the JPO; and that

(ii) Such an argument is considered to be an excessively abstract position and unreasonably limits the raisons d'etre for the legislation covering three-dimensional trademark registration.

3.5 Conclusion of the IP High Court

Based on the above analysis, the IP High Court concluded that it does not fall under Article 3.1(iii) of the Trademark Act and revoked the refusal of the JPO without going on to consider whether the configuration of the Seashell bar has acquired secondary meaning.

Interestingly, the JPO decided to abide by the court decision without filing an appeal to the Supreme Court.

Since the international registration date of this Madrid Protocol application is more than eighteen months ago, the JPO is no longer in a position to issue any additional refusal (unless the description of goods is found to be unclear or indefinite) due to the limitations laid down by the Madrid Protocol. It will thus have no alternative but to withdraw its refusal.

4. Author's Notes

In the Coca-Cola decision denying inherent distinctiveness of the Contour bottle, the Third Bench of the same court stated, as the starting point of their analysis, the basic doctrine in protecting three-dimensional marks, inter alia, as follows:

> "Consumers would view the shape of the bottle merely as being designed to better enhance its utility and the esthetics of the beverage container"; and
>
> "Even if a shape is novel and so unique that consumers would not expect it, granting protection by way of a trademark registration, which is renewable as desired, might result in the granting of permanent and excessive protection that would go beyond that given by a patent or design registration in cases where the shape derives solely from its function."

The evidence presented by the JPO demonstrating the existence of the common chocolate products causes the author to question the validity of the ruling of the Court that the level of distinctiveness of the plaintiff's chocolate bar is sufficient to enable consumers to distinguish it from others - would it not be possible for consumers to assume that the Seashell bar merely represents one variation of such known products? What impact will this decision have on other chocolate producers' ability to enjoy free competition?

Unlike the Coca-Cola Contour Bottle case, which was broadly reported by local TV news programs and by both local and foreign newspapers on the day of the delivery of the decision, this case does not yet seem to have become so broadly known, even in Japan. However, this is the first case, during ex-parte proceedings, in which the IP High Court has recognized the inherent distinctiveness of the configuration of a product per se, rather than its container or packaging. The ruling of the court in this Guylian decision will draw more attention of IP professionals and trademark practitioners before long, and indeed is likely to be explored in greater depth, perhaps from the perspective of the Coke Contour bottle case as discussed above.

*1 (Gyo-Ke)10215/2007, IP High Court, May 29, 2008
Yuasa and Hara Intellectual Property News, Vol. 25, Aug. 2008

*2 Trademark Act, Article 3.1
Any trademark to be used in connection with goods or services pertaining to the business of an applicant may be registered, unless the mark:
…
(iii) consists solely of a mark indicating, in a common manner, in the case of goods, the place of origin, place of sale, quality, materials, efficacy, intended purpose, quantity, shape (including shape of package), price, the method or time of production or use, or, in the case of services, the

location of provision, quality, articles to be used in such provision, efficacy, intended purpose, quantity, modes, piece or method or time of provision;

Case study: Bitter or sweet?

—Unfair Competition Dispute regarding FERRERO package in China

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1. Background and parties to the case

FERRERO is a world-famous chocolate company established in Italy in 1946. The FERRERO ROCHER chocolate entered the Chinese market through China Cereals, Oils & Foodstuffs Import & Export Co., Ltd. in February 1984, and had mainly been sold at duty-free shops and airport shops until 1993. FERRERO received trademark registration for FERRERO ROCHER, an oval figure and a combination thereof in China in October 1986. FERRERO has mainly been developing the market in Kuangtung, Shanghai and Peking, China, since 1993, by advertising the FERRERO ROCHER chocolate in newspapers, periodicals, etc., and has been selling it by opening shops in major department stores. It has been gradually becoming more well-known over the course of many years. The FERRERO ROCHER trademark was put on the National Important Trademark Protection List by the Administrative Authority for Industry and Commerce of the P.R.C. in June 2000. In addition, the FERRERO ROCHER chocolate was named "Jinsha" in Taiwan and Hong Kong and received trademark registration for "Jinsha" in Taiwan in June 1990 and in Hong Kong in 1993.

In April 1991, Zhangjiagang No. 1 dairy products factory registered "Jinsha" as its trademark. It then formed Mengtesha, a joint venture between Zhangjiagang No. 1 dairy products factory and a Belgian company, in December 1991. In June 1993, Zhangjiagang No. 1 dairy products factory changed its name to JiangSu Liang-Feng Food Group Co., Ltd.

FERRERO filed a demand for annulment of the unlawful registration of the trademark "Jinsha" with the Trademark Review and Appraisal Board of the P.R.C. in 1994 but was rejected. In 2002, Zhangjiagang No. 1

dairy products factory assigned the "Jinsha" trademark to Mengtesha. JiangSu LiangFeng Food Group Co., Ltd. then applied for and received trademark registration for "TRESOR DORE" in July 2003. The Jinsha TRESOR DORE chocolate was evaluated and deemed "Chinese Quality Goods" by the China National Food Industry Association in 2000 and 2001 and as "Famous Chinese Brand Goods" in 2004, and was thus exempted from food inspection. Also, the "Jinsha" trademark was recognized as a famous trademark in JiangSu Province in 2001. It has been becoming more well-known and its sales have been increasing substantially every year.

FERRERO believed that Mengtesha's Jinsha TRESOR DORE chocolate uses a package and design similar to those of the FERRERO ROCHER chocolate, and filed a complaint with Tianjin No.2 Intermediate People's Court alleging that Mengtesha's actions constitute unfair competition.

2. Procedural history of the case

The history of the case is as follows.

(1) First trial : Tianjin No.2 Intermediate People's Court
Plaintiff : FERRERO S.P.A., Italy (hereinafter "FERRERO")
Defendant : Mengtesha (Zhangjiagang) Food Co., Ltd.(hereinafter "Mengtesha")
Date of judgment : February 7, 2005
Gist of judgment : Mengtesha's actions do not constitute infringement of Ferrero's rights. FERRERO's claim is dismissed.

(2) Appellate trial : The Higher People's Court of Tianjin
Appellant : FERRERO
Appellee : Mengtesha
Date of judgment : January 9, 2006
Gist of judgment :
① The judgment of the first instance is unlawful and dismissed.
② Mengtesha shall immediately stop the act of using packaging and design infringing those of the TRESOR DORE chocolate.
③ Mengtesha shall compensate FERRERO for its economic damages, amounting to 700,000 RMB, within 15 days from the date of this judgment.

(3) Retrial : The Supreme People's Court of the P.R. China
Appellant : Mengtesha
Appellee : FERRERO
Date of judgment : March 26, 2008
Gist of judgment : The judgment of the second instance is partly upheld.
Mengtesha shall compensate FERRERO for its economic damages, amounting to 500,000 RMB, within 15 days from the date of this judgment.

3. Key issues

FERRERO ROCHER asserted unfair competitive conduct by Mengtesha under Article 5 of the Unfair Competition Prevention Law, which provides, "[A]n enterpriser shall not trade goods on the market causing damage to a competitor by using any of the unlawful measures described below…
(2) Using without authorization the unique name, package or design of famous goods or using any name, package or design resembling that of famous goods, thereby causing confusion with the famous goods of another person and causing buyers to misunderstand the identity of the famous goods;…"

The main issues were:

① Was the FERRERO ROCHER chocolate well-known before Mengtesha's "Jinsha TRESOR DORE";
② Are the package and design of the FERRERO ROCHER chocolate conspicuous; and
③ Do the package and design used for Mengtesha's "Jinsha TRESOR DORE" chocolate constitute unfair competition?

The courts decided about these issues as follows.

(1) Issue ①

Court	Locality	Famousness
Interme-diate Court	Well-known goods must be well-known in China. Namely, they must meet a regional requirement. Goods well-known abroad should not necessarily be well-known in China.The judgment on whether the goods are well-known or not depends on whether the goods are well-known by Chinese consumers.	The plaintiff's chocolate had only been sold at duty-free shops and airport shops until 1993, and has mainly been advertised and sold in Kuangtung, Shanghai and Beijing after 1993, and has only recently become well-known. The defendant's chocolate became well-known in the mid-1990s. Evidence submitted by Mengtesha indicates that the Jinsha chocolate has a larger market share and is better known than the plaintiff's goods.
Higher Court	The judgment on whether the goods are well-known or not should be based on particular market situations in China and abroad.	FERRERO is known very well in the industry. The FERRERO ROCHER chocolate had become famous in the world before it entered the Chinese market. The FERRERO ROCHER chocolate has become well-known in China through many years of advertising and sale.
Supreme Court	Well-known goods are those well-known among general consumers in China. Whether the package of goods well-known abroad should be protected in China or not depends on whether it is well-known or not among general consumers in China.	According to the date of entry into the Chinese market, sales records and circumstances including advertisement and promotion by FERRERO, there is no error in the judgment of the second instance that the FERRERO ROCHER chocolate is well-known in China.

(2) Issue ②

Court	Distinctive Package and Design
Interme-diate Court	The golden aluminum foil wrapping around the chocolate is commonly used in the chocolate industry, and cannot be monopolized by FERRERO. However, the design of the FERRERO ROCHER chocolate had been used before it entered the Chinese market and has the function of distinguishing its origin from others. Thus, the court found it to be a distinctive design owned by FERRERO.
Higher Court	The package and design used for the FERRERO ROCHER chocolate are an integral and inseparable whole, express a particular meaning and are distinctive. The Jinsha TRESOR DORE chocolate of Mengtesha uses basically the same package and design as those of the FERRERO ROCHER chocolate. As Mengtesha cannot prove that it created the package and design itself, it is recognized to have been unlawfully using the distinctive package and design of the FERRERO ROCHER chocolate.
Supreme Court	The package and design of goods should be held distinctive if they can distinguish the origin of the goods from that of others. FERRERO cannot monopolize aluminum foil, plastic packs, etc., but the package and design used for the FERRERO ROCHER chocolate have a unique character in the combination of letters, figures, colors, forms, size and other constitutional elements. Also, the package and design have become well-known among general consumers through extensive advertisement and use for many years. Consumers may have the impression that the package and design have a particular relationship with the FERRERO ROCHER chocolate. Therefore, the package and design are recognized as distinctive ones because they have the function of distinguishing the origin of the goods from that of others.

(3) Issue ③

Court	Unfair Competition
Interme-diate Court	Whether consumers may mistake the defendant's goods for the plaintiff's goods should be the basis for judging when the plaintiff's goods and the defendant's goods each became well-known and how well-known they are. Evidence indicates that the Jinsha chocolate has a larger market share and is more well-known than the plaintiff's goods. Also, the plaintiff's goods and the defendant's goods have different consumers. Their packages resemble each other, but, as they each have a trademark in a conspicuous place, consumers will not mistake one for the other because they are distinguishable by their trademarks and their manufacturers. Thus, the court found that the package and design used by Mengtesha does not infringe the rights of or unfairly compete with FERRERO.
Higher Court	As Mengtesha cannot prove that it independently created the package and design complained of by FERRERO, it is recognized to have unlawfully been using the distinctive package and design of the FERRERO ROCHER chocolate. Well-known goods must naturally be the result of the good-faith operation of business according to the rules of good faith. The results of business fostered by acts of unfair competition shall not be used as a basis for recognizing how well-known the goods are. The unlawful use of the distinctive package and design of the FERRERO ROCHER chocolate by Mengtesha has a negative influence upon the sales and reputation of the FERRERO ROCHER chocolate. Therefore, FERRERO's claim shall not be dismissed merely because the Mengtesha's Jinsha TRESOR DORE chocolate is now more well-known than the FERRERO ROCHER chocolate in the Chinese market. The actions of Mengtesha constitute unfair competition with the plaintiff. The finding of the first instance is unlawful and false.
Supreme Court	Mengtesha may create a package and design distinguishable from those of another person by using common elements used in the packaging and design of chocolate goods. However, Mengtesha shall not imitate to the point of causing misrecognition the package and design of goods of another person that distinguish the origin of that person's goods from that of others. The package and design used for Mengtesha's chocolate closely resemble those of the FERRERO ROCHER chocolate. Although the price, quality, taste, manufacturer, trademark, etc., of one are different from those of the other, consumers may misunderstand that Mengtesha's Jinsha TRESOR DORE chocolate has a relationship with the FERRERO ROCHER chocolate. Mengtesha's argument that the similar package and design will not cause misrecognition by consumers is unacceptable. The use of the package and design by Mengtesha constitutes an act of unfair competition with FERRERO. As FERRERO did not submit any evidence proving the damages suffered from these acts of unfair competition or the profit received by Mengtesha from the infringing act, the court recognized damages amounting to 500,000 RMB based on the provision of the Trademark Law regarding the amount of damages.

FERRERO "FERRERO ROCHER" Chocolate

Mengtesha "Jinsha TRESOR DORE" Chocolate

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