Selected Articles from

YUASA AND HARA

INTELLECTUAL PROPERTY NEWS

VOL. 25 August 2008

CONTENTS

Shape of COKE Bottle Recognized as 3D Trademark

Plaintiff: The Coca-Cola Company, represented by Yuasa and Hara

Defendant: Commissioner, The Japan Patent Office

Case Number: (Gyo-Ke) 10215/2007, IP High Court, May 29, 2008

1. Introduction

Toshiaki Iimura, the presiding judge of the Third Bench of the Intellectual Property High Court recently overturned the Japan Patent Office rejection of an application for the three-dimensional shape of a Coke Bottle in class 32 for cola drinks and affirmed The Coca-Cola Company's allegation that the Coke bottle per se has acquired secondary meaning. This decision not only represents the first case where the shape of a beverage container has been recognized as a three-dimensional trademark since 1997, when registration for three-dimensional trademarks started in Japan, but also constitutes a groundbreaking case wherein a trade dress with a famous word mark has been ruled to have acquired distinctiveness in relation to its shape.

2. Examination by the JPO

2.1 In 2003, The Coca-Cola Company (TCCC) filed a trademark application for a

three-dimensional mark composed solely of the shape of a Coke bottle in class 32. This applied-for trademark is colorless and does not carry any word or picture mark as shown in the photographs below:

The examiner of the Japan Patent Office (JPO) rejected the application on the ground of lack of distinctiveness, denying the applicant's arguments.

2.2 The applicant TCCC filed an appeal with the Appeal Board of the JPO. The goods were limited to "cola drinks".

With evidence including more than 60 exhibits, some of which are described in Sections 3.1 and 3.2 below,
TCCC argued, in summary, as follows:

A trademark, whether two-dimensional or three-dimensional, is rarely used independently; normally, a two-dimensional trademark(s) consisting of letters, etc. and a three-dimensional trade dress are combined when actually used in the market. It is therefore unreasonable to deny that goods can be identified from a three-dimensional trademark only for the reason that consumer are more attracted to a letter mark borne thereon. The applied-for mark has been used with the "Coca-Cola" label, both being well recognized and strongly performing a function of distinguishing the goods from others, and each trademark has individually become famous. This fact is apparent from the consumer survey and other exhibits. The examiner indeed overlooked this fact and consequently made a wrong decision.

In February, 2007, the Appeal Board found as follows:

(a) The subject trademark does not go beyond the characteristics of the containers that would be commonly applied to similar goods to enhance the functions and beauty of those goods. It cannot be said that the subject trademark has a peculiar shape or decorative shape that conveys an unexpected image for a container of "cola drinks";

(b) Any of the trademarks appearing in the Exhibits carry the letters "Coca-Cola" written in a characteristic cursive style in a central portion of the container. It is not identical to the applied-for trademark composed solely of a three-dimensional shape;

(c) Traders and consumers would regard the famous two-dimensional mark "Coca-Cola" written in a distinctive way to attract attention as an identifier to distinguish the demandant's goods from the others', and would recognize the three-dimensional shape merely as the shape of the container of the goods and would never regard it as a mark that distinguishes the demandant's goods from the others'. The three-dimensional shape of the trademark used is not or, if any, little distinctive;

(d) The applied-for trademark has a spiral groove designed for a screw cap, while some of the trademarks used do not have such groove or they are shown with the opening closed with a cap (stopper). The two trademarks cannot be regarded as identical;

(e) The registrability of the applied-for trademark should be judged basically under the Trademark Act of Japan and should not be judged based on or influenced by the circumstances in other countries;

(f) The consumer survey titled "Report of survey on whether a certain beverage bottle reminds people of a certain brand" was conducted only in Tokyo and Osaka. Moreover, as those surveyed were aged from 20 to 59, the survey was not properly conducted in terms of selecting consumer group;

(g) The survey revealed, for example, the fact that 19% and 28% of the consumers did not associate the demandant's "Coca-Cola" brand with the "colorless container" and the "colored container", respectively. It cannot be readily said from the survey that they associated the "Coca-Cola" goods based on the three-dimensional shape of the applied-for trademark. This also underpins that the survey cannot prove enough that the applied-for trademark has acquired distinctiveness through use.

On the above basis, the Appeal Board sustained the examiner's rejection and concluded:

(i) That this trademark consisted only of the shape of a bottle that may normally be applied to a beverage container and lacked inherent

distinctiveness, thus falling within the Trademark Act, Art. 3.1.3 (rejection of indistinctive indications)*1;
and

(ii) That the bottle used by the applicant differs from the trademark under the application in appearance - it was not established by the evidence that the applied-for mark had acquired secondary meaning (Trademark Act, Article 3.2)*2.

3. Appeal to the IP High Court

TCCC, represented by Yuasa and Hara's Osamu Suzuki, Kuniaki Kobayashi and Kazuhiro Nakata, filed an appeal with the IP High Court, a special division of the Tokyo High Court, alleging that both of the above rulings (i) and (ii) were incorrect. To strengthen their allegation, TCCC supplemented the original evidence with more than 70 exhibits as supporting evidence.

3.1 Inherent distinctiveness

To convince the court of the bottle's inherently distinctive features, TCCC cited a number of descriptions and publications such as:

"For its shape, the bottle is called 'hobble skirt'…"
from "50 Years of Upheaval: Visual History of Showa Era" (Coca-Cola Bottlers);

"It was changed to depict the shape of the unique 'Coca-Cola' bottle in order to prompt what the consumers have learned in connection with the bottle … To make 'Coca-Cola' totally different from others and give a message that 'Coca-Cola' is so special, the marketing team even discussed producing aluminum cans shaped like that glass bottle…" from "Marketing Games" (Toyo Keizai Shimpo-sha);

"Brief History of Fizzy Drinks Business in the US …The Coca-Cola bottle was changed to a hobble skirt shape…" from "Creation of Business: Japanization of Soft Drinks" (Bunshindo);

"The design is 'one recognizable as that of the Coca-Cola bottle even when touched in the dark' … that bottle which is considered to be classic today" from "True Histories of Hit Brands" (Tokyu Agency);

"Most perfect package among those of everyday-use items", "Coca-Cola's unique bottle is called 'global symbol of soft drinks' and this is recognized by the public" from "Legendary Management": Business History of Coca-Cola" (Mahoroba Shobo);

Other publications making similar reference to the Coke curvaceous bottle, such as "Study on Coca-Cola" (Kodansha), "Open and You'll Find it America" (Ohbunsha), "Stories of American Brands" (Hannah Campbell), "For God, Country, and Coca-Cola" (Mark Pendergrast); Books including "Commentary of Unfair Competition Law" and "Commentary of Trademark Law" (Dr. Shoen Ono), "Overview of Unfair Competition Law" (Prof. Yoshiyuki Tamura), "Paris Convention Kowa (Lecture on Paris Convention)" (Prof. Haruo Goto), "Basic Course: Design Act" (Ryoji Saito), which refer to the Coca-Cola bottle shape as a trademark having a function similar to that of brand names, for example, "(the function of a mark) is performed through such characteristic colors, shape, touch thereof, etc., as can be perceived from the Coca-Cola bottle", "From the word 'Coca-Cola', … quite a few people recall that unique bottle shape;

Certificates of foreign trademark registrations in U.S.A., Canada, U.K., Australia, Russia, etc.

After holding four hearings, however, the High Court upheld the ruling of the JPO that the shape of the Coke bottle lacked inherent distinctiveness.

The court first stated:

That the shape of any goods or container is generally adopted primarily for the purpose of enhancing their utility and functions, and for the purpose of decorating them, and also would not be recognized by consumers as an identifier of the source of goods;

That if a shape is not purely functional or decorative, others might want to adopt it and it would not be appropriate to grant a particular party, even if a first filer, an exclusive right to use a shape that contributes to the function or decoration of goods, etc.; and further

That 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.

From the above standpoint, the court ruled that even if the plaintiff had intended to provide distinctive features to the bottle for the purpose of identifying its source, the shape of the bottle would, at the time the JPO concluded its examination, be viewed by consumers as being designed such as to better enhance its utility and the esthetics of the beverage container. It agreed with the JPO that the applied-for mark did not go beyond the shape or configuration of goods or a container thereof as represented in a normal manner under Art. 3.1.3 of the Trademark Act.

This interpretation of the "inherent distinctiveness" requirement by the IP High Court (and the JPO) reflects the long disputed concern that granting registration for the shape or configuration of a product or its container, even if arbitrary and unique, would impose undue limits on other manufacturers' choices and harm free competition. It is observed that the Court made such interpretation of law in contrast to the court of the European Community which did not recognize any distinction between the shape of goods or containers thereof and other categories of marks.

While the shape of the Coke bottle is registered in a number of countries without claiming secondary meaning, the Court did not make any reference to such registrations. However, this is not so surprising as it seems to be a common understanding that the existing local law of a country and its local interpretation are supposed to be independent of those of other countries, even if due respect is given to the concept of international harmonization.

3.2 Secondary Meaning

(1) Plaintiff's Argument for Secondary Meaning

TCCC further argued that if the bottle shape is not recognized as being inherently distinctive, it has acquired secondary meaning. In support of this allegation, TCCC cited the following exhibits, among others:

Coca-Cola's annual sales report, advertising materials, listings of titles and reproductions of TV commercials;

Consumer survey reports (2003 and 2007); Statements written by university professors specializing in law, statistics, etc., local industry associations; and

Reports on actions taken by TCCC for the exclusion of activities that amount to simulating or copying use of the Coke bottle or its image.

(2) Fact-Finding

On the basis of the above, the Court found the following facts:

(a) Since launching its returnable bottle in 1957 in Japan, TCCC has stuck to the same shape;

(b) TCCC sold 2,388 million bottles at its peak in 1971 and still sells 96 million bottles a year;

(c) Amid the spending of a huge amount of money every year on sales promotion of TCCC's products, pictures of the bottle have been extensively displayed in advertising media, so that consumers may be strongly impressed by the shape, as the majority of product containers have switched to cans and PET bottles;

(d) Consumer surveys conducted in 2003 and 2007 by the plaintiff showed that approximately 90 percent of respondents picked the colorless Coke Bottle from several other bottles as the one they were familiar with, and approximately 60 to 80 percent correctly named it as “Coca-Cola”;

(e) A number of books on the history and uniqueness of the shape of the Coke bottle have been published. Esteemed trademark professionals referred in their publications to the Coke bottle as an appropriate example of a distinctive three-dimensional trademark. In addition, local beverage industry associations acknowledged in writing that the applied-for mark is to be used exclusively by TCCC;

(f) There are no other beverage containers having a similar shape in the market, and the plaintiff has made serious efforts to exclude unauthorized use of similar bottles and pictures thereof, or those that attempted to copy it; and

(g) As a result, the shape of the bottle by itself is widely recognized as a “brand symbol”.

(3) Collateral Use of the COCA-COLA Mark

In 2007 preceding the Coke case, the Court had overturned the JPO rejection of the three-dimensional shape of the Mini MAG-LITE torch on the basis of acquired secondary meaning. The Coke case, however, had a more difficult issue that had

never been resolved before; Coke had never been sold in a bottle, and rarely advertised, without bearing the famous word mark, COCA-COLA or COKE conspicuously on the body as shown below.

In the case of MAG-LITE, the word mark was, in contrast to the case of Coca-Cola, displayed at the top edge in rather thin and small letters, which scarcely attracted the attention of viewers.

(For major precedents, including the MAG-LITE case, see “Protection of Three-Dimensional Trademarks in Japan”, YUASA AND HARA INTELLECTUAL PROPERTY NEWS, Vol. 22 August 2007).

The JPO had intensively repeated their argument that since the Coke returnable bottle bore the famous word mark, COCA-COLA or COKE, in such a manner that consumers’ attention might be more readily attracted to the word mark, there was nothing to show that the shape of the bottle per se had acquired distinctiveness

apart from use with the word mark.

Because it is difficult to imagine any products on the market without any other word mark or logo appearing on them, this longstanding interpretation of the JPO has made the registration of the three-dimensional shape of a product or its container as difficult as a camel successfully going through the eye of a needle.

In other parties' earlier cases involving three-dimensional marks, consumer surveys conducted for the purpose of establishing publicity of the shapes of a product or its container had been presented. In no case, however, did the JPO, the IP High Court and its predecessor, the Tokyo High Court, affirm the veracity of their conclusion.

To overcome this difficulty and gain objective and persuasive results, TCCC carefully designed and conducted three types of consumer survey with different questions and methodologies on different occasions. Thanks to these efforts, the court made particular note from the above fact (d) that, inter alia, these consumer surveys testify to the fact that the distinctive nature of the bottle had made a strong impression on consumers and consequently that:

(i) The applied-for mark serves as an identifier, notwithstanding the difference in the mouth compared with the returnable bottle; and
(ii) Use of the word mark COCA-COLA was not necessarily indispensable to identifying its source.

The Court thus ruled that the shape of the Coke bottle had acquired secondary meaning and become recognized by consumers as an identifier of the TCCC returnable bottle, distinct from others, and specifically stated as follows:
"In actual trading, it is frequently the case that two or more marks are used on one article of goods to identify the source thereof. It is also conceivable that traders and consumers may identify the source of goods by some characteristic, whether two-dimensional or three, apart from any other mark affixed by the manufacturer. Since the distinctiveness that has been acquired in the shape of the Coke bottle is considered to be extremely strong, as backed up by the above facts (a) - (g), it is not correct to conclude that the shape per se had not acquired distinctiveness through sales and advertising simply because the bottle carried the famous COCA-COLA

word mark."

(4) Other Differences between the Applied-for Mark and Returnable Bottle

The JPO had further pointed out that the mouth of thebottle under the application was, inter alia, threaded - as opposed to that of the returnable bottle which had a mouth with a swelling ring beneath the lip.

The Court also rejected this argument, noting that the mouth of the bottle was purely functional and common, and therefore that such difference did not Hinder a finding that distinctiveness had become acquired in the bottle shape.

3.3 Conclusion

The court thus overturned the JPO's ruling and affirmed the acquisition of secondary meaning through exclusive and extensive use and advertising.

The JPO swallowed the ruling of the IP High Court without filing an appeal to the Supreme Court. The case has now been remanded to the Appeal Board for re-examination. Unless the Appeal Board finds any other ground for rejection, the shape of the Coke bottle will become the first registration for trade dress of a beverage container in Japan.

It should be noted from the analysis of this ruling that The Coca-Cola Company's victory resulted largely from their continuous efforts to maintain a high level of publicity with respect to the bottle image in consumers' minds and more significantly from their diligence in excluding from the market any simulating or copying use of their trade dress.

4. Epilogue

A month later, Nobuyoshi Tanaka, the presiding judge of the Fourth Bench of the IP High Court, issued another interesting and epoch-making decision involving a three-dimensional trademark of the GUYLIAN Sea Shell chocolate. It affirmed inherent distinctiveness based on its uniqueness of the appearance. As of today, the author has not been able to confirm whether the JPO has filed an appeal to the Supreme Court. We will report this case on a future occasion.

*1 Trademark Act, Article 3.1.3

Any trademark to be used in connection with goods or services pertaining to the business of an applicant may be registered, unless the trademark:

…

(iii) consists solely of a mark indicating, in a common manner, in the case of goods, the place of origin, place of sale, quality, raw materials, efficacy, intended purpose, quantity, shape including shape of packages, 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, price or method or time of provision;

*2 Trademark Act, Article 3.2

Notwithstanding the preceding paragraph, a trademark that falls under any of items (iii) to (v) of the preceding paragraph may be registered if, as a result of the use of the trademark, consumers are able to recognize the goods or services as those pertaining to a business of a particular person.

Kazuhiro Nakata (Mr.)

Patent & Trademark Attorney of the Trademark & Design Division

Life Cycle Management of Drugs and Patent System in Japan

1. Japanese Pharmaceutical Market

The size of the Japanese pharmaceutical market was US$56.7 billion in 2006, which accounted for about 9% of the global market (US$643 billion), second only to the US market. On the other hand, though the size of the global market for drugs expanded to US$601.3 billion in 2005, from US$280.3 billion in 1995, the size of the Japanese market has changed little. Accordingly, the Japanese share of the global market has halved over the last ten years.

Japan provides a public medical insurance system, which is carried on as a social insurance system covering all citizens. Through this insurance system, about 30% of the nation's medical expenses are covered by public funds, and all prices for medicine, including medical compensation for doctors and prices for new drugs are substantially controlled by the Japanese government. Recently, because the nation's medical expenses are expected to increase along with the aging of Japanese society, policies for constraining the nation's medical expenses have been adopted, which have significantly

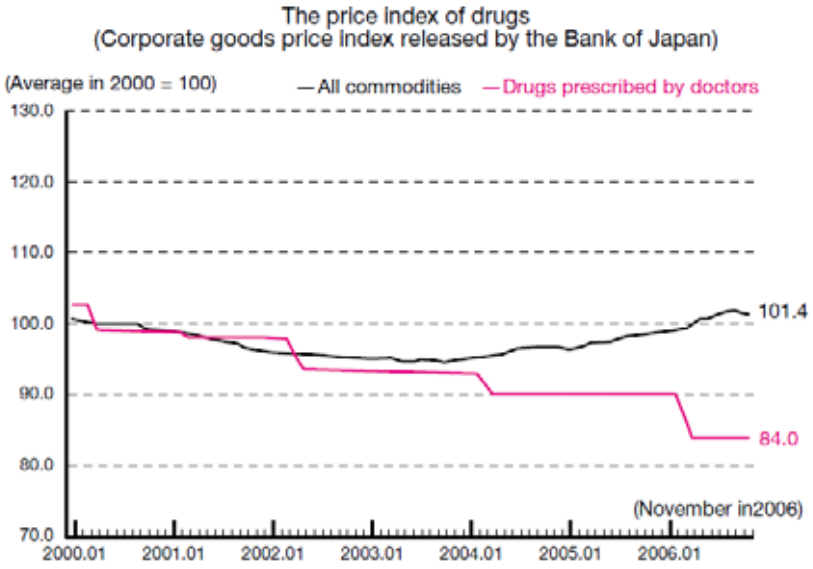
affected Japan's pharmaceutical market.

The Japanese government determines prices reimbursed by public medical insurance for each of preparations and standards of all drugs prescribed by doctors. The reimbursement price of each drug is reviewed every two years and almost all reimbursement prices of drugs are reduced, including those of new drugs immediately after their release onto the market. This system is called the "Drug Pricing System" and under the system, expenses for drugs covered by medical insurance are constrained and as a result, the size of the Japanese pharmaceutical market has been kept at a certain level in recent years. On the other hand, among major advanced nations, only Japan has a system in which the prices of new drugs immediately after their release onto the market are reduced through political action. The price index of drugs over the past several years has deviated from the general average price index and over the long term the trend has been downward.

Despite such drug price constraint policies, it is a concern in Japan that public financing of medical insurance will worsen. As a countermeasure, the government is making an effort toward the promotion of generic drug use. The market share of generic drugs is 16.8% in Japan (on a volume basis, 2004), which is significantly lower than that in the United States (56% in 2005), Germany (41% in 2004), and the UK (49% in 2004). The government has adopted a policy of expanding the market share of generic drugs by revising the form of prescriptions issued by doctors in 2006 and 2008 and aims at increasing the market share of generic drugs to 30% on a volume basis by 2012.

There are often debates in terms of constraining the nation's medical expenses as relate to policies for the domestic drug market. On the other hand, pharmaceutical companies are of the opinion that under the present drug pricing system, which determines the prices of new drugs without regard to market price, the value of innovation through research is not properly evaluated, and this obstructs the securing of adequate profits and resources for research and development to create an innovative new drug. The government has revealed its opinion in a report "New Vision for the Pharmaceutical Industry" released in 2007, which is available in English translation via the homepage of Ministry of Health, Labour and Welfare, that it is necessary to consider, in terms of promotion of the pharmaceutical industry, a mechanism in which pharmaceutical companies can enjoy returns corresponding to the risks of research and

development and innovation during the patent term of new drugs in order to properly evaluate innovation through research. The report, at the same time, refers to importance of steadily implement replacement with generic drugs as a term of patents and reexamination period under the Pharmaceutical Affairs Law expire, in order to secure sustainability of public finances for medical insurance.



(Reprinted from Future Vision of Pharmaceutical Industry, released by Office of Pharmaceutical Industry Research, 2007)

2. Life Cycle Management of Drugs

The life cycle of drugs can be recognized as having four stages: an introductory period; a growth period; a maturation period; and a declining period, similar to a general product life cycle. Drugs which hit the market after authorization by the government shift to a growth period, during which sales expand. After sales promotion activities during the introductory period and after passing the profitability point, they enter a maturation period in which they acquire profits to recoup research and development costs. Thereafter, due to the entry of generic drugs, they enter a declining period and sales decrease due to a drop in market share and price.

In the life cycle management of drugs, it is important to obtain maximum gross sales during the life cycle of the drugs. For that purpose, in addition to strategies for accelerating the start of sales during the introductory and growth periods, measures for delaying the entry of generic drugs and thereby delaying the advent of a declining period should be considered. Generic drugs are allowed to enter the market after the reexamination period has elapsed under the Pharmaceutical Affairs Law, and after expiry of the patent term covering the drugs. What is critical is how to extend the term

of patent rights protecting drugs to delay the advent of a declining period as life cycle management.

Reexamination System under the Pharmaceutical Affairs Law and Patent Term Extension System, which are closely related to life cycle management of drugs, will be explained hereinafter.

3. Patent Term Extension System

A patent term may be extended up to five (5) years upon application for registration of an extension if the patented invention could not be worked for the necessity of obtaining an approval of a drug. In this regard, not only the term of drugs but also the patent terms of pesticides may be extended in Japan. However, medical equipment, food additives and artificial colors are not eligible for extensions.

The features of the term extension system of Japan are summarized below.

(1) Applicants are limited to patent owners. In addition, patent owners and exclusive licensees or registered ordinary licensees must obtain approval for manufacturing under the Pharmaceutical Affairs Law.

(2) The period for application is prior to the expiry of the patent term of which an extension is applied and within three (3) months of the date of approval. In this regard, if it is not expected that approval for manufacturing under the Pharmaceutical Affairs Law can be obtained by the day previous to the date six months prior to the expiry of the patent term, application for registration of an extension may not be accepted after six months prior to an expiry of the patent term unless the prescribed form has been submitted by the day previous to the date six months prior to the said expiry.

(3) The term to be extended shall be the period during which the patented invention could not be worked, and it shall be the period from either the date of commencement of clinical tests or the date of registration of establishment of the patent right, whichever comes later, to the date of approval. It shall be calculated by year, month, and date, and may not exceed five (5) years.

If clinical tests were conducted overseas and then the drug was subsequently approved

as a result of conducting of clinical tests or bridging tests in Japan, the date of commencing clinical tests overseas can be regarded as the date of commencing clinical tests.

Therefore, as there are cases where it is advantageous that patent rights should be obtained as early as possible for obtaining a longer extended term, for that purpose, it is recommended that expedited examination be requested. It generally takes two or three years from filing of a request for examination for a first office action to be issued, but if expedited examination is requested, it may take as little as three (3) months.

(4) Subject of Registration of Extension

(4-1) Where there are multiple patents corresponding to one disposition, for any of the patent rights, registrations of term extensions may be approved individually. For example, if there are a patent for a chemical compound which is the active ingredient of an approved drug, a use patent for applying the active ingredient to an approved medical use and a process patent for the manufacturing process of the active ingredient, any of the said patent rights may be registered for extension individually. Further, a patent invention of formulations may be subject to registration of extension. As stated above, registration of extension is allowed under a broader scope in Japan than in the United States or Europe.

(4-2) If there are multiple dispositions corresponding to one patent right; for example, if multiple approvals different in efficacy and effect are given to a patent right for compounds which are the active ingredients of drugs, or multiple approvals are given to different compounds in a patent right which claims multiple compounds, multiple registrations of extension may be accepted based on these approvals.

(4-3) An application for patent term extension based on a later approval of a pharmaceutical with active ingredient and efficacy/effect both identical to those specified in another earlier approval (e.g., differing only in dosage form or manufacturing process) shall be refused. Therefore, under current examination standards, where the approval under the Pharmaceutical Affairs Law has already been obtained for a certain substance and usage, if the patent right is effected based on the dosage forms, etc., the said patent right is treated as not being eligible for registration of extension. Since new drugs are difficult to develop, pharmaceutical companies generally attempt to extend registration of a new patent of formulations. In the case where Takeda Pharmaceutical Company Limited requested extension of the formulation patent of Leuplin, an anticancer drug the

invention of which is named “long sustained-release microcapsule,” the Intellectual Property High Court upheld the decision which refused application for registrations of extension of the patent right based on the reasoning that it was not recognized that it was necessary to obtain the approval for manufacturing under the Pharmaceutical Affairs Law for practice of the patent invention in terms of the object (active ingredients) and usage (efficacy and effect). (Intellectual Property High Court (Administration Ke), No. 10311, 2006, judgment as of July 19, 2007)

(4-4) For an object which is actually the same as an object approved for drugs, if usage is equal to that which was already subject to disposition, application for registrations of extension shall be refused. For example, if there is a patent right in which a compound and its salts are claimed, and the drug, whose active ingredients are the sodium salt of the compound, has already been approved, the registrations of extension based on the approval of the drug, whose active ingredients are potassium salt of the compound and whose efficacy and effect is equal, is not accepted.

(4-5) Patent rights related to intermediates, or catalysts and manufacturing devices used for manufacturing of final product are not subject to extension.

(5) Validity of patent rights related to drugs whose term was extended covers only cases where a patent invention is practiced for the drugs subject to approval of manufacturing under the Pharmaceutical Affairs Law, and does not cover other cases. For details of application for registrations of extension, please refer to the following website of the Patent Office in English.

http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_tokkyo_e/1312-002_e.htm

Examination Guidelines for Patent and Utility Model in Japan

Part VI: PATENT TERM EXTENSION

4. Reexamination System under the Pharmaceutical Affairs Law

Test data supporting efficacy and safety, which are required to be submitted to administrative authorities for application for approval of new drugs, are provided for in TRIPs as an intellectual property right (Article 39, paragraph 3). In the United States and the EU, to protect test data submitted by manufacturers of new drugs, such test data are not allowed to be used for examination of approval of generic drugs for a certain period of time after approval of the new drugs.

On the other hand, in Japan, the balance of interest between manufacturers of new

drugs and generic drugs is actually regulated by the reexamination system under the Pharmaceutical Affairs Law, which inherently aims at reconfirming the efficacy and safety of drugs, not by a data protection system concerning intellectual property rights. Under this system, a party whose new drugs have received approval is obliged to have the new drugs undergo reexamination after the elapse of a certain period of time from the start of commercial availability (Re-examination Period) to confirm the safety of the new drugs (Article 14-4 of the Pharmaceutical Affairs Law). On the other hand, application for approval of generic drugs is not allowed until the Reexamination Period elapses. Therefore, entry of generic drugs is blocked for a certain period of time, producing a result similar to that under the data protection system, and manufacturers of new drugs can secure a period for recovering development costs for new drugs.

Under the reexamination system in Japan, in addition to new drugs whose active ingredients are new, for pharmaceuticals whose active ingredients were already approved, if the administration route is new, dosage and formulation is new or efficacy is new, a Reexamination Period is granted.

Reexamination and Data Protection Period

Subject Drugs	Japan	U.S.A.	EU
New active ingredients	8 years(10 years for rare disease drugs, etc.)	5 years	8 years (+ two years reversed for marketing)
Formulation for new administration route	6 years	3 years	None
New dosage, new formula-tion	4 to 6 years	3 years	None
New efficacy	4 to 6 years	3 years	1 year(only the efficacy is treated as a benchmark)

Reexamination Period of drugs whose active ingredients are new had previously been six (6) years, in general, but the Reexamination Period of drugs whose active ingredients are new, which was approved after April 2007, was extended to eight (8) years in general on request for extension of a Reexamination Period from new drug manufacturers. As a result of two years extension of the period for generic drugs to enter the market after the approval of new drugs, it is expected that additional new drugs which are not protected by patents will be commercially profitable and able to be developed. In particular, it is expected that there will be an increase in introduction of new drugs which have not been sold in Japan as they are not protected by patents,

although they are sold in the United States and Europe, and that such increase will contribute not only to the promotion of the pharmaceutical industry but also to enhancement of choices at the site of medical treatment.

Application for approval of manufacturing generic drugs is made after the elapse of the Reexamination Period, and the drug price is listed after the approval is obtained, and then sales will commence. Price listing of generic drugs was made annually, but it took nearly one year to commence sales of drugs depending on the timing of obtaining approval, which was regarded as a problem. To improve this problem, price listing of generic drugs twice a year has been in effect in July and November since 2007. In this regard, the timing of price listing of generic drugs will be changed to May and November in 2009.

To be published in the next issue
5. Patents relating to medicinal invention
6. Litigation for injunction over generic drugs
(1) Procedures for price listing of drug prices of generic drugs
(2) Cases

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

Amendment of License Registration System

Introduction

On April 18, 2008, a law amending portions of the Patent Law, etc., was promulgated, and a system to enforce registration in connection with the right to obtain a patent at the stage of application was established. As a part of this effort, a review was conducted with respect to the system used for the registration of licenses generally. It is expected that this review of the registration system will lead to more widespread utilization of the registration system in licensing practice than is currently the case.

The amended Law contains (i) a review of the license registration system, whose contents are introduced in this article, (ii) an expansion of the period during which a request may be filed for a trial appealing an examiner's decision of refusal under the Patent Law, Design Law or Trademark Law, (iii) the expansion of the list of countries for which electronic exchange of documents to obtain priority is permitted under the Patent Law and Utility Model Law, (iv) reduction in fees under the Patent Law and Trademark Law, and (v) the introduction of an account transfer system for the payment of fees.

This amended Law will be enforced from a date specified by a Cabinet Order within one year from the date of promulgation (April 18, 2008). However, the reduction in fees referred to in (iv) will be enforced from a date specified by a Cabinet Order within three months from the date of promulgation, and the introduction of an account transfer system for the payment of fees described in (v) will be enforced from January 1, 2009.

Upon inquiry, the Patent Office indicated that for an exclusive licensee or a non-exclusive licensee to work an invention claimed in a pending application under a license agreement executed prior to the enforcement date of the amendment, it is possible to satisfy the requirement for assertion of the license against third parties by enforcing registration after such enforcement date.

1. System to Enforce Registration in Connection with Licenses at the Application Stage

(1) Background of Amendment

In recent years, universities, Technology Licensing Organizations (TLOs), venture companies, etc., have been utilizing, as a valuable property right, the right to obtain a patent that is at the stage of application. A patent applicant may decide to grant a license to work an invention claimed in the pending application. The number of transfers of such rights to obtain patents related to pending applications is increasing.

However, under the current Patent Law, there is no provision for licensing before a patent right comes into existence, nor is there any registration system. Therefore, under the current system, if the right to obtain a patent is transferred to a third party before the patent right comes into existence, there is no means of asserting a license against the transferee. Moreover, if the owner of the right to obtain a patent goes bankrupt prior to registration establishing a patent right, a licensee has no means of satisfying the requirement for assertion of the license against third parties, and there

is a possibility that a trustee in bankruptcy will terminate the license agreement. These circumstances create a potential risk for companies that are preparing for or conducting business based upon a license obtained at the stage of application. In addition, if a small or medium-sized venture company wants to grant only a license of the right to obtain a patent related to a pending application, but the potential licensee wants to avoid the risk that the small or medium-sized venture company will go bankrupt or other similar risks, the small or medium-sized venture company will likely be forced to transfer the right to obtain the patent itself.

(2) Outline of the Amendment

Licensing at the stage of application, which is implemented practically, is a commitment to allow the exclusive working of a patented invention after a patent right comes into existence, and thereby provides a guarantee to a licensee preparing to do business. Its legal characteristics are deemed to be centered on an “exclusive license or non-exclusive license granted on the condition precedent that registration establishing the target patent right is established.” In order to protect such licensing, a “provisional exclusive license”, a “provisional non-exclusive license”, and a system for the registration of these licenses have been newly established under the Patent Law. By contrast, since utility model rights take a short period of time for registration to be granted, no provisional licensing system was established for them.

1) Provisional Exclusive License (Article 34-2 of the Patent Law After Amendment)

A person having the right to obtain a patent may grant a provisional exclusive license regarding the patent right to be obtained based upon his or her right to obtain a patent, to the extent of the statements which were made in the description, scope of claims or drawing(s) originally attached to the application form used for his or her patent application. When registration establishing the patent right is subsequently effected with respect to the patent application related to the provisional exclusive license, the provisional exclusive license will lapse, and, instead, an exclusive license will be deemed to have been granted on such patent right.

2) Provisional Non-Exclusive License (Article 34-2 of the Patent Law After Amendment)

A person having the right to obtain a patent may grant a provisional non-exclusive license regarding the patent right to be obtained based upon his or her right to obtain a patent, to the extent of the statements which were made in the description, scope of

claims or drawing(s) originally attached to the application form used for his or her patent application. When registration establishing the patent right is subsequently effected with respect to the patent application related to the provisional non-exclusive license, the provisional non-exclusive license will lapse, and, instead, a non-exclusive license will be deemed to have been granted on such patent right.

3) Establishment of Registration System (Item (IV) of Paragraph (1) of Article 27 of the Patent Law After Amendment)

A system for the registration of the provisional exclusive license and provisional non-exclusive license was established. The establishment, maintenance, transfer, modification, lapse or restriction on disposal of a provisional exclusive license or provisional non-exclusive license will be registered in the patent registry maintained at the Patent Office. Registration required in order for a provisional exclusive license to take effect (Article 34-4 of the said Law). Registration is also required in order for a provisional non-exclusive license to be asserted against third parties, and when such registration is effected, the provisional nonexclusive license will be effective against a third party who subsequently acquires the right to obtain a patent related to the said provisional non-exclusive license (Article 34-5 of the said Law).

4) Division of Application (Paragraph (5) of Article 34-2, Paragraph (5) of Article 34-3 of the Patent Law After Amendment)

In the event of a division of a patent application, the provisional exclusive license, or the provisional non-exclusive license, etc., will be deemed to have been granted regarding one or more patent rights to be obtained based upon the right to obtain a patent in connection with one or more new patent applications after the division, to the extent provided for by action establishing the provisional exclusive license or provisional non-exclusive license. On a related point, there is no special provision for amendments to patent applications, since a provisional exclusive license or provisional non-exclusive license is construed to remain in force to the extent provided for by action establishing the provisional exclusive license or provisional non-exclusive license.

5) Right to Claim Compensation (Paragraph (3) of Article 65 of the Patent Law After Amendment)

Pursuant to the current Patent Law, after registration establishing a patent right, the applicant for the patent may claim compensation against a person who worked

the invention claimed in the application after the laying open of said application (paragraphs (1) and (2) of Article 65 of the Patent Law). However, it has been provided that an applicant for a patent can not claim compensation from a provisional exclusive licensee or from a provisional non-exclusive licensee, even if said licensee works the invention claimed in the patent application before the patent right comes into existence.

6) Waiver or Withdrawal of Patent Application (Article 38-2 of the Patent Law After Amendment)

In order for an applicant for a patent to waive or withdraw his or her patent application after the registration of a provisional exclusive license or one or more provisional non-exclusive licenses, the applicant must obtain the consent of the registered licensee of the provisional exclusive license or all of the registered licensees of one or more provisional non-exclusive licenses.

2. Restriction on Disclosure of Registration Matters

(1) Background of Amendment

Under the current system for the registration of a non-exclusive license, etc., all details of the registration, including, without limitation, the names of the licensor and licensee, the scope of the non-exclusive license, and the amount of consideration, are disclosed to the public (paragraph (1) of Article 186 of the Patent Law). However, since the existence and details of a license agreement constitute a business strategy or trade secret of a company, there is a strong need to require that they be kept secret. The current registration system is not utilized very much, and the registration rate of non-exclusive licenses of patent rights in Japan is estimated at approximately 1%. It has been pointed out that one of the reasons for this is the requirement that registration matters be disclosed to the public.

(2) Outline of Amendment

It has been provided by the amendment that registration matters for a non-exclusive license regarding a patent right or utility model right which are subject to a strong interest in non-disclosure to the public will be disclosed only to specific interested persons (paragraph (3) of Article 186 of the Patent Law, paragraph (1) of Article 55 of the Utility Model Law after amendment). For provisional non-exclusive licenses, disclosure will be similarly restricted.

On the other hand, an exclusive license is a strong right which has exclusivity to the extent that it has been established. The influences it exerts on third parties are strong, and the necessity of public notice is therefore also strong. For this reason, as under the current practice, all registration matters will be disclosed. For provisional exclusive licenses, all registration matters will be similarly disclosed.

3. Review of Registration Matters

Under the current system, when the amount of consideration, or the method or due date of the payment thereof is provided for, such provision will be treated as a necessary registration matter subject to disclosure (item (ii) of paragraph (1) of Article 44, item (ii) of paragraph (1) of Article 45 of the Patent Registration Order). However, there is a strong need to require that the amount of consideration for a license be kept secret. Moreover, under the recent practice in connection with license agreements, there are cases in which a license and various special provisions are provided in an integrated manner, or in which more than one right is granted collectively. Thus, in many cases, it is difficult to identify the consideration for the granting of each specific license. In addition, the reality of the situation is that such consideration often undergoes changes depending on economic conditions, etc.

For these reasons, studies are being made with the goal of eliminating the amount of consideration for a license from registration matters subject to public disclosure by an amendment to the Patent Registration Order, which will be made incidentally to this revised Law.

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