Issue17 (March 2021)

Japan Patent & Trademark Update

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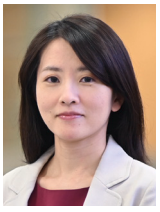

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1. Introduction

The timing of a possible generic entry is a major concern for both originators and generic companies. In Japan there is no data exclusivity system. Instead, the terms of patents covering existing products and the re-examination period provided in pharmaceutical regulations prevent generic entries. This article provides the overall information you need to understand about the laws, regulations and practices when examining generic entry into the Japanese market. Specifically, we will use practical examples to explain: (i) how patents and re-examination periods constitute the exclusivity of drugs in Japan (sections 2 to 3), (ii) how the regulatory authority handles applications for approval and drug price listings, in relation to the patents on the original drug, i.e., "patent linkage" issues (section 4), (iii) how to assess the timing of generic entry (section 5), and (iv) when and how rights can be exercised against generics (section 6).

In this article, "generic" refer to a drug that contains the same active pharmaceutical ingredient ("**API**"), with the same administration route, indication and dosage regimens, and the same clinical effects/actions as an existing "originator drug." "Biosimilar" (i.e. a drug that has the same quality, safety and efficacy as an existing biotechnology-derived drug that has been approved as a "new drug with a new API") is a different category from "generics"; however, the explanations given herein also generally apply to biosimilars.

2. Protection by patents

During the term when there are valid third-party patents that cover the product, generics may not be manufactured, sold, etc. as they would constitute infringements, even though a certain scope of working an invention for clinical trials may be exempted as detailed in section 6. Depending on such third-party patent, approval for a generic may not be rendered during the patent term in the first place, as detailed in section 4.

Patent term extension

Under the Patent Act, if there is a period during which it is not possible for a patentee to work a patent invention due to the need to obtain a marketing approval ("**MA**") for a pharmaceutical product, the term of the patent right (20 years from the application date) may be extended for a maximum of five years. The patentee needs to file an application in order to

register a patent term extension ("**PTE**"). A PTE is applied and registered based on each MA that had prevented the working of the invention. Applications for registration of a PTE need to be filed within three months from the date of each relevant MA and cannot be filed after the expiration of the original patent term. If it is found that the patented invention could have been worked without waiting to obtain the MA on which the application is based, the application for extension registration will be rejected. A patentee may apply for a PTE for multiple patents based on one MA, and one patent may, as in Example 1 below, have multiple PTEs based on each MA.

Scope of protection by an extended patent term

Where a PTE is registered, the extended patent right is effective only with regard to the working of the patented invention of the product specified as the subject of the MA that constitutes the grounds for the extension registration, i.e., the product identified by "the usage, ingredient (not limited to the API), dosage, form, administration and indication"), and is not effective against any other working of the invention (Article 68-2 of the Patent Act). Any product substantially the same as such specific product will be considered to be within the scope of the extended patent right.

Explanatory Example 1

Patent A(original patent term: until August 13,2024)	
PTEs	PTE 1 based on approval 1: Until April 13, 2028
	PTE 2 based on approval 2: Until August 13, 2029
Marketing approvals for "Product A(50mg tablet)"	
MA1 (on July10,2019)	For indicating the treatment of disease D1 by using 100 mg/day
MA2 (on June15,2022)	For adding an indication of treatment of disease D2 by using 100 mg/day

Let's look at an example where the patentee of Patent A is the marketing authorization holder ("**MAH**") of Product A (50 mg tablet) containing substance S as the API, which is covered by Patent A that claims "substance S for treatment of a disease selected from D1, D2 and D3". The patentee may file for PTEs based on approval 1 (PTE 1) and approval 2 (PTE 2), respectively. During the original patent term until August 13, 2024, Patent A is effective to the full extent of the claimed scope, i.e., enforceable against any infringing product containing substance S for use in treating disease D. After the expiration of the original term, Patent A is enforceable only against "any product containing substance S, in the form of a 50 mg tablet" and with regard to the indication of "disease D1, by using 100 mg/day" from August 14, 2024 to April 13, 2028, and "disease D2, by using 100 mg/day" from August 14, 2024 to August 13, 2029.

3. De-facto exclusivity by "re-examination period" under pharmaceutical regulations

The re-examination period is a post-marketing surveillance period required in the pharmaceutical regulations under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the "**PMD Act**"). During the re-examination period, if someone other than the applicant of the approved item intends to apply for MA for another item whose **API**, etc. are identical to the approved item, submissions cannot be abbreviated, while after the re-examination period of the previously approved item has passed, other applicants can file for an MA application with the data and materials abbreviated to some extent. As such, the re-examination period works as an exclusivity period for existing drugs. The durations of re-examination periods from the approval date are designated by the Minister of Health, Labour and Welfare (the "**Minister**") within the range stipulated under the PMD Act. A relevant notification issued by the Ministry of Health, Labour and Welfare (the "**MHLW**") provides general principles for the designation for each drug category as in the table below.

Duration of re-examination periods

	Category	General Principle
(1)	New orphan drugs (i) first approval of an indication (ii) with new administration (iii) combination of existing orphan drugs	(i) 10 years (ii)/(iii) more than 6 years to 8 years
(2)	Other new drugs so specified by the Minister	10 years
(3)	New drugs with new API (excluding (1) and (2))	8 years
(4)	New drugs designated as "Specified Use" [This includes certain scope of pediatric drugs]	4 years to less than 6 years
(5)	New drugs with new indications (excluding (1): (i) designated as "Sakigake" drugs. (ii) if the indications of the prior approved drug are those of orphan drugs, but include no other indications. (iii) other than (i) and (ii).	(i) more than 6 years to 8 years (ii) 5 years and 10 months (iii) 4 years
(6)	New drugs with new dosage regimen but the API and the administration are the same or substantially the same as an existing drug.	4 years
(7)	Other new drugs	6 years

Regardless of the category of drugs, the Minister may extend the re-examination period to a period not exceeding 10 years, if the Minister believes it is particularly necessary.

4. "Linkage" between generic applications and patent status of originator drug

Patents on an existing drug and generic approval

In practice under an MHLW notice: (i) if a patent exists at the expected approval date for the API of the originator drug and it will therefore not be possible to manufacture the API, the generic drug will not be approved; and (ii) if a patent exists for some of the indications, dosage and administration of the originator drug, such patented indications, etc. will not be approved for the generic, while the Minister may approve a generic drug if the marketing of the applied drug for other effects and/or dosage regimens is possible. As a result, if original drug O, for example, indicates diseases A and B, if the MAH of drug O holds patents 1 and 2 covering diseases A and B respectively, and if the patent period for patent 1 has expired while patent 2 is still effective, after the expiration of the re-examination periods of drug O for both diseases A and B, a generic drug can be applied and approved for the indications of disease A, without including B. This is referred to as a "*Mushi-kui Shinsei* (skinny label)" or an "Application for Basic Efficacy." Please note that the fact of a generic application having been filed will neither be made officially public or individually notified to the originator companies.

Patent information

Unlike the Orange Book in the U.S., there is no specific system in Japan for publishing patents covering new drugs. Patent information relevant to an originator drug can be submitted to the MHLW, typically with the timing of an application for MA. However, submission is not mandatory. The MHLW makes the above-mentioned decision on whether to approve a generic drug only to the extent it is aware from information submitted by the relevant originator company, and does not make a substantial decision on patent infringement. Further, submitted information will not be disclosed or made available to the public. Generic makers are therefore required to perform a full search by themselves with regard to relevant patents prior to applying for MA.

"Prior Consultation" before drug price listing

As Japan has adopted a nationwide universal health insurance system, generics not listed on the National Health Insurance Drug Price List ("**NHI Price List**") would not have market competitiveness in terms of pricing against originator drugs. Therefore, it is practically essential for a generic maker to submit an application to be listed on the NHI Price List, after obtaining MA. Under the relevant notice, the MHLW requests that, when there is concern about the patent issue, the parties involved (i.e. the generic maker and the originator company) shall hold "Prior Consultation" to coordinate the issue and, for the generic maker, apply for listing only when it believes that the item can be stably supplied. Note that the MHLW does not proactively order or coordinate such Prior Consultation. Instead, it is normally the originator company who takes the lead in commencing Prior Consultation, as with normal patent negotiations or disputes, by giving a warning letter to the generic maker after it becomes public that MA has been granted for the generic. If Prior Consultation is initiated, it is necessary for the originator company to notify the fact to the MHLW which then sets a deadline and has each party report the results of the Prior Consultation by the deadline. The MHLW also conducts an interview with the generic maker in order to determine whether or not a stable supply of the generic after the listing on the NHI Price List is likely, including asking about the status of the Prior Consultation. The MHLW again does not make a substantial decision on patent infringement. Instead, it will check from the generic maker the reasons why it believes there is non-infringement and how it would handle a possible lawsuit and injunction. Then, if the MHLW considers that the generic maker can reasonably demonstrate that it can still take some measures to ensure a stable supply of the drug, the MHLW may approve listing of the generic on the NHI Price List, even if the originator and the generic maker had not reached an agreement through Prior Consultation. When a patent concern remains, the MHLW may ask the generic manufacturer, before making an official notice for listing, to submit a letter which states, for example, that if the supply of the drug is expected to be difficult due to a patent dispute, it acknowledges that the generic product may be removed from the NHI Price List.

5. When does a generic entry become possible?

Now we explain how to assess the timing when generic entry becomes possible under the above-mentioned laws, regulations and practices. The important steps for this assessment are to survey the re-examination periods, search the patents covering the originator product, and check the patent terms (including PTEs). In order to determine the expiration date(s) of the re-examination period for the original drug, if the original drug has multiple approvals (e.g. the first approval for the original application and the additional approvals for applications for additional indications), it is necessary to investigate the existence and expiration date of the re-examination period for each approval. As for the search of relevant patents and the PTE dates, since there is no comprehensive book listing all relevant patents of the originator drug, this search should be done carefully. It is also necessary to determine whether one or more extensions have been registered for the patents, and if so, the scope covered by each extension should be carefully examined.

Explanatory Example 2

Let's examine the possible timing of generic entry in Example 2 when there is an originator drug, Product O (50 mg tablet) containing substance S as the API, having indications for diseases D1 and D2, that is on the market. Suppose MA 1 and MA 2 were obtained for diseases D1 and D2, respectively; there were two patents (Patents 1 and 2) that cover Product O; and PTEs-1 and 2 and PTE-3 were registered. Generic entry is not possible for either disease D1 or D2 before the expiration of both of the re-examination periods for MAs 1 and 2 (i.e. before July 9, 2029). From July 10, 2029, a generic having the indication of disease D1 can be approved. Due to PTE-3, it is only after August 6, 2038 when generics having the indication of disease D2 become possible.

Explanatory Example 2

Marketing approvals for Product O(50mg tablet)	
MA1 (July 10,2019)	(i) Indication: treatment of disease D1 by using 100 mg/day (ii) Re-examination period: until July 9, 2029
MA2 (June 15,2022)	(i) addition of indication: treatment of disease D2 (ii) Re-examination period: same as the remainder of MA 1 (i.e. until July 9, 2029)
Patents covering Product O	
Patent 1 (original patent term: until August 13, 2024) that claims "substance S"	
PTEs	PTE-1 based on MA 1: until April 13, 2028
	PTE-2 based on MA 2: until August 13, 2029
Patent 2 (original patent term: until September 8, 2035) that claims "substance S for treatment of disease D2"	
PTEs	PTE-3 based on MA 2: until August 5, 2038

In practice, it would take a few additional months to reach the market after obtaining MA, as the generic maker would have to wait until the listing on the NHI Price List. If the application for listing on the NHI Price List is submitted soon after obtaining the MA and even if things go smoothly, the NHI Price List is revised only during specific months of the year, depending on the category of the items. In current practice, the revisions are usually in June (for those approved until February) and December (for those approved until August) for generics and in May (for those approved until March) and November (for those approved until September) for biosimilars.

6. Exercising of rights against generics

Seeking injunction etc. based on patent infringement

As in typical patent infringement disputes, the available procedures are injunctions (either preliminary injunctions through provisional procedures or permanent injunctions through litigation) for the cessation or prevention of infringement, and/or compensation for damage through litigation against patent infringement by a generic drug. The requirements for granting a preliminary injunction in a patent infringement case are: (1) the existence of infringement (an invalidity argument may be considered); and (2) the need to avoid substantial damage or imminent danger to the patentee's right. In the case of permanent injunctions, such "need" is not a requirement and an injunction is automatic. The "need" requirement of (2) above is a consideration of the balance between the patentee's rights and the potential harm that may be caused to the respondent in the case of a preliminary injunction being admitted. In the case of prescription drugs, obtaining MA, or filing for listing on the NHI Price List at the latest, is sufficient to fulfill the "need" requirement, as infringing acts such as manufacture, import, sale, etc. of the product become likely and imminent when such event has occurred.

Research Exemption

The act of filing for MA does not itself constitute a working of an invention, and therefore does not constitute patent infringement. How about clinical trials? Article 69.1 of the Patent Act sets forth a limitation on the scope of a patent right by providing that a patent right is not effective against the working of a patented invention conducted for "experimental or research purposes". According to established court precedents, if there is a patented invention of a chemical substance or of a pharmaceutical including such substance as an API, a third party's act during the patent term of production of the patented substance/product and conducting of tests necessary for obtaining the data to be attached to an application for MA as a generic drug (having the same API as the patent) for marketing after the expiration of the patent term shall be considered for "experimental or research purposes" and thus does not constitute patent infringement. Therefore, a company may perform clinical trials of a generic drug for the purposes of marketing it after the expiration of the patent of the new drug and may file for and obtain MA for the generic drug even before the expiration of the patent term without infringing the patent. Note that manufacturing for stock piling before the patent expiration exceeds the scope of such exemption and would constitute infringement.

Typical timing

Accordingly, a patentee typically starts taking actions somewhere between the granting of MA and the filing for/listing on the NHI Price List.

7. Conclusion

As summarized herein, the scope of exclusivity needs to be carefully reviewed based on the information on re-examination periods and patents for each indication.

2. Newly Registered Examples of GUI, Building, and Interior Designs

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Introduction

One (1) year has passed since the revised Design Act (the "Revised Act") came into effect, and we have introduced the first registrations granted under the Revised Act on our "Japan Trademark / Design Update" issued on November 10, 2020. In this article, we provide the updates on the registrations thereafter.

Number of Design Applications for Newly Protected Subject Matter

On January 15, 2021, the JPO updated the number of design applications for newly protected subject matter, following to October 1, 2020 (see our previous newsletter "Issue 16", article 2), as follows:

	GUIs	Buildings	Interiors
Number of design applications	685	294	172

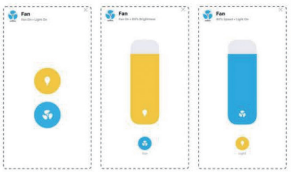
https://www.jpo.go.jp/system/design/gaiyo/seidogaiyo/document/isyou_kaisei_2019/shutsugan-jokyo.pdf

Since October 1, 2020, the number of the applications for newly protected subject matter is increasing at a steady pace, proving that user's interests in proactively protecting the new subject matter. In particular, the number of GUI applications has significantly increased by 230.

Examples of Registrations for GUI Designs

115 design gazettes in relation to GUI designs were published as of February 1, 2021.

(1) JP 1676441 for "Image for operating electronic devices" by Apple Inc.



(2) JP1678243 for "Image for displaying information" by MITSUBISHI ELECTRIC CORPORATION

3) JP1675966 for "Image for icon" by SKYCOM Corporation

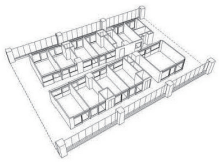
Under the Revised Act, as shown in the above examples, applicants are able to seek protection solely for the images without specifying the physical device such as a smartphone or tablet.

Examples of Registrations for Building Designs

52 design gazettes in relation to building designs were published by February 1, 2021.

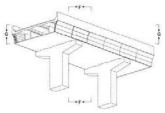
(1) JP1675717 for "House" by Sekisui House, Ltd.

(2) JP1672637 for "Hospital" by MITSUBISHI JISHO SEKKEI INC



(3) JP1673492 for "Restaurant" by SAKURA COFFEE

(4) JP1678411 for "Bridge" by NIPPON STEEL ENGINEERING CO., LTD.



(5) JP1674140 for "Office building" by OBAYASHI CORPORATION

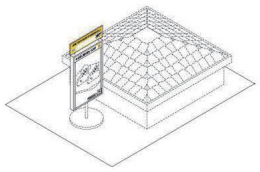
These cases show that applicants are now able to seek protection for real estate and large constructions under the Revised Act. As seen in Case (2), an interior design of a building can be protected as a building design.

Examples of Registrations for Interior Designs

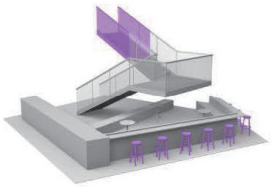
17 design gazettes in relation to interior designs were published by February 1, 2021.

(1) JP1671152 for "Bookstore interior" by CULTURE CONVENIENCE CLUB CO., LTD.

(2) JP1672911 for "Sales floor interior" by every Inc.



(3) JP1673700 for "Office floor interior" by OKAMURA CORPORATION



(4) JP1677595 for "Interior for plant control room" by Yokogawa Electric Corporation

It is interesting that protections were sought no only for B-to-C designs as shown in Cases (1) and (2), but also for B-to-B designs as shown in Cases (3) and (4) which are generally not designed to be seen by the public, showing the applicants are not limited to particular field of business.

Conclusion

The number of the applications for newly protected subject matter is still increasing at a steady. As we are yet at the very early stage of the new design system, it is important to stay alert of the trends of other companies and build a system / policy to properly protect the designs.

3. High Hurdle Revealed for Registration of a Position Mark

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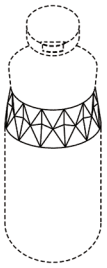
Introduction

In April, it will be six years since position marks became registrable as trademarks in Japan, and 109 such marks have been registered as of February 8, 2020. Several IP High Court ("IPHC") decisions were issued concerning the inherent registrability of position marks last year. The examples of such registrations and court decisions have made it abundantly clear that there is quite a high hurdle for registration of position marks in Japan.

Recent IPHC Decision Denies Registrability of a Position Mark

On December 15, 2020, the IPHC issued a decision denying the distinctiveness of a position mark consisting of a sequence of a 3-D diamond-shaped design placed around the bottle container of a nationally popular BBQ sauce. ((Gyo-ke) 10076/2020)



App. No. 2015-47397
Ebara Foods Industry, Inc.
Goods: Barbecue sauces in Class 30
Detailed description of mark:
The mark consists of 3D shapes

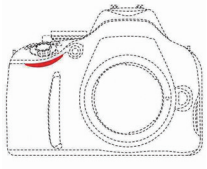
The IPHC found that a design featuring a series of 3-D diamond-shapes has been commonly adopted for the packaging containers of liquid products for functional (i.e. easy to grip) and aesthetic purposes, and that the applicant itself had admitted such purposes for the adoption of the design for its product bottle on its website and in the industry journal. The IPHC also pointed out that bottles for BBQ sauces usually have labels with the name of the product or brand, etc. above or below such design, and consumers therefore do not generally consider such 3-D shapes placed around the bottle as indications of the origin of products but rather as a design

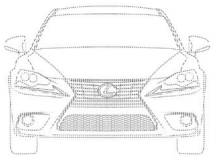
adopted to improve the function or attractiveness of the goods. Although the applicant's BBQ sauce has a market share of over 54% and has had strong visibility in TV commercials and other media, the IPHC decided not to approve of the acquired distinctiveness of such design, stating that the 3-D diamond-shaped design was not particularly featured or introduced as a source indicator in the applicant's promotional materials. The applicant submitted a secondary meaning survey asking BBQ sauce consumers to identify the names of products by looking at four different packaging bottles of BBQ sauces without labels, but the IPHC did not accept such survey as evidence based on the flaws in the choice of bottles (it did not include any bottles that had similar bottle shapes to those of the applicant).

A position mark is a trademark consisting of any character(s), figure(s), sign(s), or 3-D shape(s), etc. which is specified by its position on the relevant goods. Needless to say, the merit of a position mark registration is to enable the registration of a simple figure, shape etc. which is not distinctive by itself, as long as the specific position of such figure, shape, etc. generates distinctiveness. However, this IPHC decision shows that the position itself can rarely add sufficient distinctiveness to a simple or common figure, shape, etc. In practice, this means that the establishment of acquired distinctiveness as a result of use is usually required in order for a position mark to be registrable.

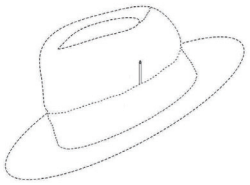
Examples of Position Mark Registrations Approved in Japan

The majority of the 109 registered position marks incorporate distinctive elements, such as names of the brands, graphics or devices, which are already inherently registrable as regular word/device trademarks. On the other hand, the following marks consisting solely of simple patterns, shapes, figures, etc. have faced distinctiveness objections and been approved for registration based on acquired distinctiveness as a result of use, except for one International Registration for a mark consisting of a matchstick emerging from the band of a hat.

 Reg. No. 6118238 (Nikon Corporation)	Detailed description of mark: The mark consists of a device affixed to the upper part of the front grip part of a camera or digital camera. (Actual product)

 Reg. No. 6076621 (Toyota Motor Corporation)	Detailed description of the mark: The mark consists of two L-shaped 3-D designs positioned above the bumper underneath the headlights that are located on the sides of a radiator grill on a front face of a car. (Actual product)

 Reg. No. 6034112 (Nisshin Foods Holdings, Co., Ltd)	
Detailed description of mark: The mark consists of a combination of devices applied around the upper and lower part of a product container. (Actual product)	

 Int'l Reg. No. 1339230 (Fouquet Trading, LLC)	Detailed description of mark: The mark consists of a matchstick emerging from the band or ribbon of a brimmed hat or cap. (Actual product)

Conclusion

A position mark consisting of an indistinctive mark is basically considered as lacking distinctiveness unless it has acquired distinctiveness. However, it is quite rare that a position mark is used by itself. Rather, it is usually used together with other distinctive elements, such as a brand logo and a product name, which are often found by the Court to be functioning as a source indicator and thereby become encumbrances to proving a secondary meaning of a position mark. Trademark owners may need to take a strategic approach to secure a position mark registration, such as emphasizing the position mark as a source indicator and avoiding claiming functional or aesthetic effects of the position mark in promotional materials and activities, and monitoring and removing a third-party use of a similar position mark for the relevant goods and maintain exclusivity. The above-noted IPHC decision and examples of position mark registrations illustrate the high hurdle that needs to be cleared in order to obtain a position mark registration without a distinctive element.

4. About TMI

Since our establishment on October 1, 1990, TMI Associates has grown rapidly to become a full-service law firm that offers valuable and comprehensive legal services of the highest quality at all times. Among TMI's practice areas, intellectual property (IP) – including patents, designs and trademarks – has been a vital part of our firm from the beginning, and we boast an unrivaled level of experience and achievement in this area.

Organizational Structure

TMI, has a total of more than 1,000 employees worldwide, including over 570 IP/Legal professionals, comprised of 493 attorneys (Bengoshi), 85 patent/trademark attorneys (Benrishi), and 39 foreign law professionals.

Attorneys (Bengoshi)	493
Patent / Trademark Attorneys (Benrishi)	85
Foreign Law Counsels	7
Foreign Attorneys	32
Advisors	6
Management Officers	3
Patent Engineers, Staff	398
Total	1,024

(As of March 1, 2021)

Areas of Expertise

TMI's practice covers all aspects of IP, including patent/trademark prosecution, transactions (e.g., patent sales, acquisitions and licensing), litigation, invalidation trials, oppositions, due diligence activities and import suspension at Customs. TMI handles over 8,200 patent/trademark/design applications and over 20 IP lawsuits per year and TMI's patent team covers all technical fields, including electronics, computer software, telecommunications, semiconductors, chemicals, biotechnology, pharmaceuticals, and mechanical fields.

Electronics	28	Chemical	12
Mechanical	17	Bio, Pharma	7
Design (overlap included)	6	Trademark	21
IP Lawyers	80		

Awards

In recent times, TMI and our attorneys/patent attorneys have been the proud recipients of awards every year. Here is a selected list of just some of the many awards and recognitions that TMI has recently received.

Contact and Global Offices

If you have any questions or requests regarding our services, please contact our attorneys and patent attorneys who you regularly communicate with or use our representative address.

TMI Associates

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6-10-1 Roppongi, Minato-ku,
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Offices - Tokyo, Nagoya, Kobe, Osaka, Kyoto, Fukuoka, Shanghai, Beijing, Yangon, Singapore, Ho Chi Minh City, Hanoi, Phnom Penh, Silicon Valley, London, Bangkok