GETTING THE DEAL THROUGH

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GLOBAL COMPETITION REVIEW

Pharmaceutical Antitrust

2012

in 29 jurisdictions worldwide

Contributing editor: Marleen Van Kerckhove

Published by
Getting the Deal Through
in association with:

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Anti-Monopoly Law Office LLC
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Pharmaceutical Antitrust 2012

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Pharmaceutical Antitrust 2012
Published by
Law Business Research Ltd
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London, W11 1QQ, UK
Tel: +44 20 7908 1188
Fax: +44 20 7229 6910

ISSN 1757-6288

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

Law Business Research

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Japan

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs?

The primary piece of legislation setting out the regulatory framework for the marketing and authorisation of pharmaceutical products is the Pharmaceutical Affairs Act (No. 145 of 1960) (PAA).

The Health Insurance Act (No. 70 of 1922) (HIA) sets out the pricing of drugs covered by public health insurance (these drugs are roughly equivalent to drugs used in medical institutions and prescription drugs). Under the Japanese health insurance system, generally all residents of Japan are required to be covered by health insurance, and most of the drugs used in, or prescribed by, medical institutions are covered by this mandatory insurance. Under the health insurance system, the total prices of drugs that medical institutions and dispensing pharmacies charge to insurers (national government or others) and insured persons are calculated according to a notification of the Ministry of Health, Labour and Welfare (MHLW). Generally, prices of over-the-counter (OTC) drugs are not subject to the notification. This chapter focuses primarily on drugs covered by public health insurance.

2 Which bodies are entrusted with enforcing these regulatory rules?

The MHLW is responsible for the regulatory rules regarding pharmaceutical products, as well as regulatory filings and approvals.

The Pharmaceuticals and Medical Devices Agency (PMDA), which is one of the incorporated administrative agencies under the supervision of the MHLW, has responsibility for reviewing and for approving of medical drugs and devices, provides guidance and advice for clinical trials, assesses compliance data submitted with approval applications in relation to good clinical practice (GCP), and provides other services.

Each prefectural governor also has authority concerning pharmaceutical products, including the power to grant licences for dispensing pharmacies (PAA, article 4) and retail pharmacies (PAA, articles 25 and 26) and to inspect licence holders under the PAA (article 69).

3 Which aspects of this legislation are most directly relevant to the application of competition law to the pharmaceutical sector?

The PAA is not directly relevant to the application of competition law to the pharmaceutical sector. Some provisions of the PAA regarding regulations on advertising may relate to competition law in a broad sense.

Competition legislation and regulation

4 Which legislation sets out competition law?

The main body of Japanese competition law consists of the Act concerning Prohibition of Private Monopolisation and Maintenance of Fair Trade (No. 54 of 1947) (Antimonopoly Act, AMA).

The Act against Unjustifiable Premiums and Misleading Representations (No. 134 of 1962) (PRA) governs the area of trade description (such as labelling or advertisement of products), as a special law of the AMA. Based on article 3 of the PRA, the Japan Fair Trade Commission (JFTC) has issued a notice named the 'Restriction on the Provision of Premiums in Medical Drug Business, Medical Equipment Business, and Sanitary Survey Business' (Notice No. 54 of 1997).

5 Are there guidelines on the application of competition law that are directly relevant to the pharmaceutical sector?

There are no such guidelines. However, there are three fair competition codes directly relevant to the pharmaceutical sector.

Based on PRA, article 11, companies or trade associations may, upon authorisation from the Secretary-General of the Consumer Affairs Agency (CAA) and the JFTC, establish a rule to prevent unjust inducement of customers and to secure fair competition with respect to premiums or representations. These rules in the pharmaceutical sector include:

- the Fair Competition Code regarding the Restrictions on the Provision of Premiums in the Business of Manufacturing and Sales of Medical Drugs;
- the Fair Competition Code regarding the Restriction on the Provision of Premiums in the Business of Wholesale of Medical Drugs; and
- the Fair Competition Code regarding the Restriction on the Provision of Premiums in the Business of Medical Machinery.

6 Which authorities investigate and decide on pharmaceutical mergers and the anti-competitive effect of conduct or agreements in the pharmaceutical sector?

The JFTC is the main competition agency in Japan, and it investigates and decides upon antitrust issues in the pharmaceutical sector, as well as in any other field unless a criminal case is initiated. In 2009, the CAA was established to protect the interests of consumers, and is mainly responsible for the enforcement of the PRA.

7 What remedies can competition authorities impose for anti-competitive conduct or agreements by pharmaceutical companies?

The remedies that the JFTC can impose are cease-and-desist orders, and orders for the payment of surcharges (administrative fines). The CAA can impose cease-and-desist orders on the violation of the PRA.

The JFTC also has the authority to request that the Public Prosecutors' Office lay charges, which could lead to criminal sanctions for certain types of antitrust violations, such as hard-core cartels. However, the number of these criminal cases is usually limited to one or two per year.

Remedies to be imposed against pharmaceutical companies are not different from those against companies in other sectors.

8 Can private parties obtain competition-related remedies if they suffer harm from anti-competitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

In addition to the right to claim damages under general tort law (article 709 of the Civil Code), private parties have competition-related remedies under the AMA. One of the remedies is the right to demand injunctions.

If a person is suffering, or likely to be suffering serious harm, due to an act that can be characterised as 'unfair trade practices' (which is defined in the AMA and a notification of the JFTC), they can demand the suspension or prevention of the act of violation (AMA, article 24). A typical example is a case of unjust low price sales, where a company can request an injunction due to claims that its competitor's pricing is too low (typically, below cost).

Another remedy under the AMA is the right to claim damages (article 25). This right to claim damages is different from the right to claim damages under general tort law in that the defendant cannot be exempted from the liability to indemnify the plaintiff by proving that there exists no wilfulness or negligence on their part. However, in order to claim damages based on this right, the cease-and-desist order or the order for payment of surcharges must have become final and conclusive before the plaintiff claims the right (AMA, article 26).

9 May the antitrust authority conduct sector-wide inquiries? If so, have such inquiries ever been conducted into the pharmaceutical sector and, if so, what was the main outcome?

Although there is no specific provision in the AMA, it is interpreted in such a way that the JFTC may conduct necessary inquiries, including sector-wide inquiries, provided addressees of such inquires voluntarily respond to them. In 2006, the JFTC conducted inquiries into the distribution of drugs covered by public health insurance, with a particular focus on generic drugs. In its final report issued in 2006, the JFTC warned that brand-name pharmaceutical companies should not provide doctors with false information about cases of the use of generic drugs; describe generic drugs to doctors as being generally defective, based on a particular generic drug having been found to have a defect in manufacturing; or describe generic drugs generally as having a low quality, based on exceptional or rare results of tests.

10 Is the regulatory body for the pharmaceutical sector responsible for sector-specific regulation of competition distinct from the general competition rules?

There is no regulatory body responsible for sector-specific regulation distinct from general competition rules.

11 Can antitrust concerns be addressed with industrial-policy type arguments, such as strengthening the local or regional research and development activities?

Antitrust concerns would not generally be addressed with industrial-policy type arguments.

12 To what extent do non-government groups play a role in the application of competition rules to the pharmaceutical sector?

There are a number of non-government groups relating to the pharmaceutical sector. Although their petitions or opinions do not primarily focus on antitrust issues, their petitions or opinions may have some impact on antitrust policy in the pharmaceutical sector. They include the Japan Generic Medicines Association and the Japan Pharmaceutical Manufacturers Association.

Review of mergers

13 To what extent are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

Like other mergers, the merging of two pharmaceutical companies is reviewed according to the substantive test of whether the merger 'may be substantially to restrain competition in any particular field of trade'.

In a merger review, the JFTC used to characterise the market of prescription drugs as an industry where the competitive pressure from the downstream market was intense. That is to say, the JFTC stated that with regard to medical drugs, customers of pharmaceutical companies (ie, wholesalers and medical institutions) had been conducting a variety of efforts to procure less expensive products, and competition among wholesalers for medical institutions was high (*Sankyo/Daiichi*, 2005; *Yamanouchi/Fujisawa*, 2005). We believe that this feature of intense competitive pressure from the downstream market contributed to the JFTC's greenlighting of these mergers.

However, in another more recent case, the JFTC stated that competitive pressure from the downstream market to the prescription drug market was not intense, because patients had little control over which drugs their doctors would prescribe to them, and doctors had little incentive to prescribe more affordable drugs to patients, since patients pay the cost of prescription drugs (*Kirin Holdings/Kyowa Hakko*, 2008). This may indicate the change of JFTC's recognition of the features of the prescription drug market.

14 How are product markets and geographic markets typically defined in the pharmaceutical sector?

In both the *Sankyo/Daiichi* and *Yamanouchi/Fujisawa* merger cases (see question 13), the JFTC defined the product market of medical drugs in light of the Anatomical Therapeutic Chemical Classification (ATC) code developed by the European Pharmaceutical Marketing Research Association. This ATC code classifies medical drugs in accordance with the main drug efficacy of the main ingredients. While there are four levels of classification in this ATC code, from level 1 to level 4 (level 4 is the most detailed classification), the JFTC noted that the product market of medical drugs should be generally defined in accordance with the level 3 classification.

In the pharmaceutical sector, geographic markets are generally defined as the market of Japan.

15 In what circumstances will a product and geographical overlap between two merging parties be considered problematic?

A product and geographical overlap between two merging parties will be problematic, if the merger 'may be substantially to restrain competition in any particular field of trade'. 'Competition' here includes both actual and potential competition (AMA, article 2(4)). Once the Tokyo High Court held that 'substantially to restrain competition' means that because of reduced competition, a particular company or a group of particular companies brings a situation where it can dominate a market by setting, at its own will and freely to some extent, prices, qualities, quantities and other conditions (*In re Toho and Shin-Toho*, Tokyo High Court judgment, 7 December 1953).

The Guidelines to Application of the Antimonopoly Act Concerning Review of Business Combination of the JFTC, which were most recently amended effective as of 1 July 2011 (the Merger Guidelines), provide more detailed guidelines to the review of horizontal mergers. According to the Merger Guidelines, when relevant products are characterised to be differentiated by brands etc, the merger will be problematic if parties to a merger sell products highly substitutable for each other and other competitors' products are not so highly substitutable to the products of the parties to the merger, because the parties could increase the price of the product without losing many sales after the merger. Even when relevant products are characterised to be homogeneous, a merger of competitors will be problematic if other competitors cannot increase their output because of their limited production capacity or for other reasons.

On the other hand, the Merger Guidelines set forth the following safe harbour rules; horizontal mergers will not be considered problematic if:

- the Herfindahl-Herschmann Index (HHI) after the merger is not more than 1,500;
- the HHI after the merger is over 1,500 but not more than 2,500 while the increment of HHI does not exceed 250; or
- the HHI after the merger is over 2,500 while the increment of HHI does not exceed 150.

In addition, there is a quasi-safe harbour which is initiated when the HHI after the merger is not more than 2,500 and the combined market share is 35 per cent or smaller.

16 When is an overlap with respect to products that are being developed likely to be problematic?

When product X, that is being developed by a party to a merger is, if launched, expected to become influential competing product with existing product Y of another party to the merger, and the launch of the product X is likely, such overlap between the products X and Y may be problematic. In the *Kirin Holdings/Kyowa Hakko* case of 2008 (see question 13), the JFTC cited such overlap involving product under development as one of the reasons why the merger between the parties should come with a remedy to cure such a problem.

17 Which remedies will typically be required to resolve any issues that have been identified?

In the area of merger control, the most typical remedies would be to require the parties to a merger to divest themselves of overlapping products or assets. Other typical remedies include: allowing competitors access to bottle-necking facilities owned by the parties; providing competitors with technological assistance; and granting competitors or customers with the right to procure overlapping products on a production-cost basis.

Please note, however, that in Japan the JFTC has never issued an order of divestiture or any other remedies in merger control for the last 30 years because almost all merger cases that might invite interests of the JFTC had been dealt with through an unofficial prior consultation process with the JFTC (the 'prior consultation') until June 2011, and parties had almost always voluntarily followed the remedy resulting from negotiation with the JFTC, if one is required. The JFTC, however, abolished the prior consultation system effective as of 1 July 2011, and we may see some orders of divestitures in the near future.

18 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

Mere acquisition of one or more patents or licences will not be subject to merger reporting under the AMA.

Anti-competitive agreements

19 What is the general framework for assessing whether an agreement or practice can be considered anti-competitive?

Roughly, the AMA prohibits three types of activities:

- private monopolisation (activities to exclude or control the business activities of other entrepreneurs);
- unreasonable restraint of trade (activities to restrict or conduct business activities mutually with other entrepreneurs in such a manner as to fix, maintain or increase prices, limit production or products, or other similar matters); and
- unfair trade practices (activities stipulated by the AMA or designated by the JFTC as activities that unjustly discriminate against other entrepreneurs, deal at unjust prices, deal with another party on such terms as will unjustly restrict the business activities of the other party, and other similar practices).

It should be noted that, under the AMA, while private monopolisation and unreasonable restraint of trade require the level of restriction on competition to be substantial, a tendency to impede competition would be sufficient for the purpose of unfair trade practices (see also question 26). It can be said that private monopolisation corresponds approximately to the abuse of dominant position under EU competition law, and unreasonable restraint of trade includes almost all illegal cartels.

20 Describe the nature and main ramifications of any cartel investigations in the pharmaceutical sector.

There have been three cartel investigations into the pharmaceutical sector since 2000. In December 2000, the JFTC started investigating a cartel case where 10 wholesalers of medical drugs in Miyagi Prefecture (in the north of Japan) entered into an agreement not to take away existing customers from others, and fixed prices of medical drugs to be offered to medical institutions. The participants to the cartel admitted the violation and the JFTC issued a recommendation decision (which is similar to a consent decree) in January 2002.

In June 2002, the JFTC announced that it could not find a violation despite its investigation into importers of medical materials to be used by orthopaedists including artificial hip joints.

On 31 March 2008, the JFTC issued a cease-and-desist order and order for payment of surcharges against participants in bid rigging involving selective tendering procedure for medical X-ray devices by certain local governments.

21 To what extent are technology licensing agreements considered anti-competitive?

The Guidelines for the Use of Intellectual Property under the Antimonopoly Act issued by the JFTC on 28 September 2007 (the IP Guidelines) set out to what extent technology licensing agreements are considered to be anti-competitive. Examples of agreements ancillary to technology licence agreements that are in principle considered to be anti-competitive are those that:

- prohibit a licensee from research and development of the licensed technology or competing technologies;
- oblige a licensee to assign improved technology, or grant an exclusive licence for that technology back to a licensor; or
- oblige a licensee to sell products utilising a licensed technology at a price designated by a licensor.

The IP Guidelines further cite, as examples of less but still potentially anti-competitive ancillary agreements, agreements that are considered anti-competitive to the extent that their effect may be to impede fair competition, ie, agreements that:

- restrict a licensee from using licensed technology even after the expiration of the patent right to the licensed technology;

- oblige a licensee, beyond the necessary extent, to procure raw materials, etc, necessary to use licensed technology, only from suppliers designated by a licensor,
- prohibit a licensee from selling products using licensed technology to persons other than those who are designated by a licensor;
- prohibit a licensee from selling or manufacturing competing products; or
- oblige a licensee to pay an amount of royalties, which is not calculated according to the use of licensed technology.

On the other hand, according to the IP Guidelines, in principle, it is not considered as unfair trade practices for a licensor to:

- restrict the purpose of a licence (such as a licence only for either domestic sales or export);
- restrict the period of a licence;
- restrict the location of production; or
- set a minimum requirement in relation to the amount of production.

22 To what extent are co-promotion and co-marketing agreements considered anti-competitive?

The anti-competitive effect of co-promotion and co-marketing agreements will be evaluated on the basis of a so-called rule of reason. These agreements can be pro-competitive, because they can reduce transaction cost or result in improved economies of scale. This is particularly true where promotion or marketing by one of the firms involved is too risky and the relevant pharmaceutical products cannot be sold in Japan without co-promotion or co-marketing. On the other hand, such agreements may be considered anti-competitive, because they are in most cases agreements among competitors and may reduce competition between the parties to some extent.

To reduce the risk of such agreements being considered anti-competitive, it would be advisable not to prohibit parties to such co-promotion or co-marketing agreements from promoting or marketing the products through their own distribution channel. On the other hand, if there is no provision or mechanism mandating participants to make efforts to sell products in such agreements, and therefore it is apparent that the sole purpose of the agreements is to stabilise the price of the product, then it would be more likely that the agreements are regarded as anti-competitive.

In 1975, the JFTC issued a cease-and-desist order against eight manufacturers of a live vaccine made to protect pigs from hog cholera to renounce an agreement to supply the vaccine only to an association that the manufacturers established, as well as an agreement on the assignment of production among them.

23 What other forms of agreement with a competitor are likely to be an issue? Can these issues be resolved by appropriate confidentiality provisions?

An agreement with a competitor is most likely to be deemed as anti-competitive if it is characterised as a hard-core cartel. On the other hand, a joint venture can be pro-competitive and is generally evaluated on the basis of the rule of reason.

The JFTC stated in 2004, in response to a consultation request, that it was not against the AMA for two pharmaceutical companies to establish a joint distribution department (or channel) for medical drugs. This was as long as the exchange of information was blocked by a firewall and the competition between the manufacturing and sales departments of these pharmaceutical companies survived the establishment of the joint distribution department. The JFTC did admit that if each company had access to information regarding the sales of the other company, such access could be used to avoid competition.

24 Which aspects of vertical agreements are most likely to raise antitrust concerns?

Vertical agreements are typically categorised as unfair trade practices among the three types of violations under the AMA. In the pharmaceutical sector, resale price maintenance, one of the unfair trade practices, would most frequently raise antitrust concerns.

In 1991, the JFTC ordered Eisai Co Ltd, one of the leading pharmaceutical companies in Japan, to withdraw its directions to retainers that Eisai's vitamin E products be sold at the retail price stipulated by Eisai and that retailers should not resell the vitamin E products to other retailers, as it held that these directions constituted 'unfair trade practices'. The JFTC further prohibited Eisai from:

- investigating the status of the resale price maintenance and resale from a retailer to other retailers by trial purchases;
- tracking the channels of resale of products to other retailers by placing hidden lot numbers on the products; and
- placing the name and telephone numbers of retailers on products they deal with.

The JFTC also ordered Eisai to make its corrective actions, as listed above, known to retailers and consumers.

25 To what extent can the settlement of a patent dispute expose the parties concerned to liability for an antitrust violation?

There has not been any case where the settlement of a patent dispute was challenged as an antitrust violation. There are no guidelines for the settlement of a patent dispute and an antitrust violation either. However, theoretically speaking if competitors reach a settlement of a patent dispute and the settlement includes provisions that substantially restrain competition in a particular field of trade, the competitors will be held liable for an unreasonable restraint of trade.

Anti-competitive unilateral conduct

26 In what circumstances is conduct considered to be anti-competitive if carried out by a firm with monopoly or market power?

The AMA does not require a firm to have a monopoly or a certain level of market power for it to be held liable under private monopolisation. That said, because the restraint has to be 'substantial' for the purpose of private monopolisation, it is considered that market share of the violator (or combined market share of the violators) shall be substantially large in a particular field of trade (see the last paragraph of this question and question 27). There are two types of conduct that may be deemed private monopolisation: exclusion of competitors and controlling of competitors. To the extent that a firm excludes or controls the business activities of other firms and causes a substantial restraint of competition in any relevant market, the conduct of this exclusion or control will be considered to be private monopolisation and therefore against the AMA.

Anti-competitive unilateral conduct can also be recognised as constituting 'unfair trade practices', as long as this conduct falls within one of the categories stipulated by the AMA or designated by the JFTC. Under unfair trade practices, a firm will be held liable if it commits one of such activities and the activity tends to impede fair competition.

It is generally thought that a 'substantial restraint of trade' (the standard under private monopolisation) requires a higher degree of anti-competitiveness than the 'tendency to impede fair competition' (the standard under unfair trade practices). Because most activities of private monopolisation overlap with those of unfair trade practices, private monopolisation (because of its higher standard of anti-competitiveness than unfair trade practices) has only been enforced in a very limited number of cases.

27 When is a party likely to be considered dominant or jointly dominant?

There is no definition of 'dominant' or 'jointly dominant' under the AMA. The meaning of the term 'dominant' may be different depending on the context in which the term is used, and the consequence of a firm being considered dominant is not clear. Nonetheless, the Guidelines for Exclusionary Private Monopolisation under the Antimonopoly Act issued by the JFTC on 28 October 2009 state that the JFTC, when deciding whether to investigate a case as Exclusionary Private Monopolisation, will prioritise the case, among others, where the market share of a firm exceeds approximately 50 per cent. Thus, as a rule of thumb, a firm with market share of more than 50 per cent will likely be considered dominant in the context of exclusionary type of private monopolisation and should use more caution than other companies.

28 Can a patent holder be dominant simply on account of the patent that it holds?

No, a patent holder cannot be generally dominant simply because it holds the patent. In Japan, the relevant market tends to be defined broadly compared to in the US or the EU, so the mere holding of patent rights generally does not lead to a dominant position.

However, the IP Guidelines state that if certain technology is used by many competitors in a certain industry and it is difficult for them to develop circumventing technology or to switch to other technology, then that relevant technology may be defined as the market. In such an exceptional case, a patent holder could be held dominant largely because of the patent it holds.

29 To what extent can an application for the grant of a patent expose the patent owner to liability for an antitrust violation?

There has not been any case where a patent owner was held liable for an antitrust violation because of the application for patent.

In the area of trademark application, there has been a case of abuse of trademark applications where a dominant local newspaper company filed applications, in order to solely prevent a new entry and with no intention to use, for nine trademarks relating to the name of local newspapers to be used in the same region. Although the dominant local newspaper company withdrew all applications, in 2000 the JFTC issued a recommendation decision (see question 20) to prevent it from engaging in the same type of activity, because these activities were a part of exclusionary conduct that fell under private monopolisation (*In re Hokkaido Shimbun*). However, in the area of patent applications, such arguments would be quite difficult because the filing of applications for patent can seldom be exclusionary as opposed to filings for trademarks, no matter how many applications are filed.

The IP Guidelines do not suggest such a possibility either, even though they state that acquisition of technology used by competitors, followed by refusal to license, or collection of technology by competitors without any intention to use them, could violate the AMA.

30 To what extent can the enforcement of a patent expose the patent owner to liability for an antitrust violation?

Article 21 of the AMA stipulates that the provisions of the AMA shall not apply to acts recognisable as the enforcement of a patent. However, it is generally interpreted that the enforcement of a patent cannot be without limitation and the AMA should apply even to the enforcement of a patent. The IP Guidelines stipulate that any business activity that may seemingly be an enforcement of a right cannot be 'recognisable as the enforcement of the rights' under article 21, provided that it is found to deviate from or run counter to the purposes of the intellectual property system, which is namely to motivate firms to realise their creative efforts and make use of technology, in view of the purpose and manner of the conduct and the scale of its impact on competition.

The IP Guidelines state that, in principle, it will not raise anti-competitive concerns for a rightholder of a technology to refuse licensing his or her technology, which is typically deemed as the enforcement of a patent. However, the IP Guidelines provide exceptional cases that may raise anti-competitive concerns, including where:

- companies participating in a patent pool agree to refuse to grant a licence to new entrants;
- a firm obtains from a rightholder a right to an influential technology that is used by many other firms in the same industry, and then refuses to license to other firms; and
- a firm collects all rights to technology that may be used by competitors without any intention to use them, and then refuses to issue a licence.

31 To what extent can certain life-cycle management strategies expose the patent owner to liability for an antitrust violation?

The JFTC has never raised an issue of life-cycle management strategies in regard to an antitrust violation.

Historically, brand-name pharmaceutical companies used to sue generic pharmaceutical companies in order to delay the entry of a generic drug, based on the ground that conducting tests necessary for an application of product-specific approval under article 14 of the PAA during the effective term of the right to a patent that is used in the generic drug is patent infringement. However, in 1999 the Supreme Court put an end to the argument by holding that such testing would fall under 'working of the patented invention for experimental or research purposes' and thus not be considered an infringement of patent rights.

Following this decision of the Supreme Court, it is said that brand-name pharmaceutical companies are trying to delay the entry of generic drugs in another way, ie, on the ground that there is an infringement of patents related to the manufacturing method.

32 Do authorised generics raise issues under the competition law?

Although the JFTC has never openly reviewed competition issues regarding the practice of authorised generics, the practice should generally be pro-competitive, unless anti-competitive ancillary agreements attached to the licence that authorises the generics outweigh the pro-competitiveness.

33 To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise infringe antitrust rules?

There has not been any case reported in which courts or the JFTC took the specific features of the pharmaceutical sector into account when examining an antitrust issue. However, in a case referred to in question 23, the JFTC accepted the parties' statement that the medical drugs at issue had to be able to be supplied in a prompt and stable manner, even in cases of large-scale natural disasters. In this case, the JFTC might have implicitly taken the specific features of the pharmaceutical sector into account. It is difficult for the specific features of the pharmaceutical sector to provide an objective justification for hard-core cartels, but they could be taken into consideration to a certain extent, especially in the cases of collaboration among competitors (which is subject to rule-of-reason review), private monopolisation, unfair trade practices (excluding per se violations like resale price maintenance) and merger clearances.

Update and trends

On 28 April 2011, the Supreme Court of Japan rendered a long-awaited judgment, upholding the judgment of the Intellectual Property High Court (IPHC) on 29 May 2009, to correct the misinterpretation by the Japan Patent Office (JPO) of patent holders' rights under the Patent Act (PA) to extend the duration period of patent rights regarding drugs and provide pharmaceutical companies with rights to extend its patents that they deserved under the PA.

As a statutory background, under the PAA, any person intending to market a drug shall, for each product, obtain a marketing approval of the minister of health, labour and welfare (article 14 of the PAA). Each 'product' is identified by various factors including a name, ingredients, quantities, structure, administration and dosage, method of use, efficacy and performance. In other words, two drugs are considered different 'products', and therefore a separate approval is required for their marketing if at least one of these identifying factors is different. On the other hand, under the PA, although the duration of a patent right ends, in principle, on the 20th anniversary of the filing date of the patent application (article 67, paragraph 1 of the PA), that duration may be extended for up to five years if the patented invention was unable to be practised because an approval (such as an approval to market drugs) was necessary for the practising of the patent invention (article 67, paragraph 2 of the PA).

Before the judgment of the IPHC, it was a JPO's practice that, where there existed a marketing approval with respect to Drug A (the 'prior approval') and a manufacturer of Drug B, based upon a patent, with the same 'active ingredients' and 'efficacy' as Drug A, applies for an extension of patent right under article 67, paragraph 2 of the PA, the JPO did not grant an extension, even if the manufacturer of Drug B was required to obtain a marketing approval with respect to Drug B because Drug B was considered a different 'product' since one of the identifying factors was different (for example, Drug A being in tablet form and Drug B being in granulated form). This practice was apparently against the language of the PA, because the PA stipulates that the JPO shall grant the extension except for the limited cases specified by the PA, with the exception relevant to the present case providing, 'where the approval was not necessary for the practising of the patented invention' (article 67-3, paragraph 1, item 1 of the PA). We assume that the JPO intended to avoid overprotection of patents and possibly to prompt launch of generic drugs after the duration period of patent rights.

The plaintiff, Takeda Pharmaceutical Company Limited, successfully challenged the JPO's practice at the IPHC, and the Supreme Court affirmed the IPHC's decision, holding that the JPO shall not reject the extension of the duration of plaintiff's patents because of the existence of the prior approval if the prior drug was not covered by the technical scope of any of the claims of the plaintiff's patented invention. On 28 December 2011, the JPO announced the change of its policy to extend the duration of patent rights in accordance with the Supreme Court judgment.

34 Has there been an increase in antitrust enforcement in the pharmaceutical sector in your jurisdiction? If so, please give an indication of the number of cases opened or pending and their subject matters.

No.

35 Is follow-on litigation a feature of pharmaceutical antitrust enforcement in your jurisdiction? If so, please briefly explain the nature and frequency of such litigation.

No.

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PHARMACEUTICAL ANTITRUST 2012 ISSN 1757-6288