Pharmaceutical Antitrust 2021

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Getting The Deal Through

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Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

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For further information please contact editorial@gettingthedealthrough.com

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Japan

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PHARMACEUTICAL REGULATORY LAW

Regulatory framework

1 | What is the applicable regulatory framework for the authorisation, pricing and marketing of pharmaceutical products, including generic drugs?

The primary piece of legislation setting out the regulatory framework for the authorisation and marketing of pharmaceutical products is the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (No. 145 of 1960) (the Act).

The Health Insurance Act (No. 70 of 1922) 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 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). Prices of over-the-counter (OTC) drugs are not subject to the notification. This chapter focuses primarily on drugs covered by public health insurance.

Regulatory authorities

2 | Which authorities are entrusted with enforcing these rules?

The MHLW is primarily responsible for the enforcement of these rules, but considerable scope (including matters related to authorisation) is entrusted to the Pharmaceuticals and Medical Devices Agency.

Pricing

3 | Are drug prices subject to regulatory control?

Under the health insurance system, traditionally, fee-for-service calculation has been the general method of calculating the prices of drugs. However, the growing exception is consideration of drugs used in hospitals that meet certain requirements for certain patients hospitalised in general beds. Under what is called the Diagnosis Procedure Combination/Per-Diem Payment System (DPC/PDPS), the consideration of drugs used in hospital during the hospitalisation is included in the DPC/PDPS part of the service fee, and the fee-for-service calculation is not applied.

Prices of drugs when sold through the distribution chain (ie, before being used in hospitals or dispensed) and prices of OTC drugs are not subject to regulatory control.

Distribution

4 | Is the distribution of pharmaceutical products subject to a specific framework or legislation? Do the rules differ depending on the distribution channel?

The Act specifically regulates the distribution of pharmaceutical products by wholesalers, pharmacies and others, and via the internet.

Intersection with competition law

5 | Which aspects of the regulatory framework are most directly relevant to the application of competition law to the pharmaceutical sector?

The Act is not directly relevant to the application of competition law to the pharmaceutical sector. That said, some provisions of the Act regarding regulations on advertising may relate to competition law in a broad sense as they come under consumer protection.

COMPETITION LEGISLATION AND REGULATION

Legislation and enforcement authorities

6 | What are the main competition law provisions and which authorities are responsible for enforcing them?

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) (the Antimonopoly Act (AMA)).

The AMA sets out the basic rules of competition law. In general, the AMA prohibits three types of activity, as follows:

- private monopolisation: activities to exclude or control the business activities of other enterprises;
- unreasonable restraint of trade: activities to restrict or conduct business activities mutually with other enterprises 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 Japan Fair Trade Commission (JFTC) as activities that unjustly discriminate against other enterprises, deal at unjust prices, deal with another party on terms that will unjustly restrict the business activities of the other party or other similar practices (eg, boycott, unjust price discrimination, predatory pricing, resale price maintenance, abuse of a superior bargaining position and other practices).

While private monopolisation and unreasonable restraint of trade require the level of restriction on competition to be substantial, a tendency to impede fair competition would be considered sufficient for the purpose of unfair trade practices.

Other important acts with aspects of competition law include the Act against Unjustifiable Premiums and Misleading Representations

(No. 134 of 1962) (PRA), which prevents unjustifiable premiums and representations (including labeling or advertisement of products), and the Unfair Competition Prevention Act.

The JFTC is the main competition agency in Japan, having jurisdiction over the pharmaceutical sector, as well as any other field. In 2009, the Consumer Affairs Agency (CAA) was established to protect the interests of consumers, and is mainly responsible for the enforcement of the PRA.

Public enforcement and remedies

7 What actions can competition authorities take to tackle anticompetitive conduct or agreements in the pharmaceutical sector and what remedies can they impose?

The remedies that the JFTC can impose are cease-and-desist orders and orders for the payment of surcharges (administrative fines). The Secretary General of the CAA can impose cease-and-desist orders on the violation of the PRA and, effective from 1 April 2016, can also issue orders for the payment of surcharges on certain types of violations (limited to certain misleading representations) 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 hardcore cartels. However, the number of such criminal cases usually does not exceed one per year.

Private enforcement and remedies

8 Can remedies be sought through private enforcement by a party that claims to have suffered harm from anticompetitive conduct or agreements implemented 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, 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 as a result of an act that can be characterised as 'unfair trade practices', 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 because of 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 by proving that there exists no wilfulness or negligence on their part. However, to invoke this right, the cease-and-desist order or the order for payment of surcharges issued by the JFTC must have become final and conclusive (AMA, article 26).

Sector inquiries

9 Can 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?

It has been 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 2015, the JFTC and Competition Policy Research Centre (an arm of the JFTC dedicated to research and study) jointly conducted inquiries on competition in the pharmaceutical sector, with a particular focus on generic drugs.

However, in June 2017, the JFTC issued the Survey on LNG Trades. It relied on reports submitted in response to orders to produce a report based on article 40 of the AMA, which has not been invoked for approximately 40 years. As such, something similar to a sector inquiry in Europe may target the pharmaceutical sector in the near future.

Health authority involvement

10 To what extent do health authorities or regulatory bodies play a role in the application of competition law to the pharmaceutical sector? How do these authorities interact with the relevant competition authority?

It does not appear that the Ministry of Health, Labour and Welfare (MHLW) is playing a significant role in the application of competition law to the pharmaceutical sector. While the MHLW is sometimes called upon to state its view where there are agendas for the JFTC that are relevant to matters under the jurisdiction of the MHLW, the MHLW's role does not seem to go beyond that. For example, the 2015 report on generic drugs does not discuss the MHLW's position in terms of competition.

NGO involvement

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

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

Pursuant to the Consumer Contract Act, certain consumer groups found to meet certain standards (qualified consumer groups) may seek an injunction on behalf of a class of consumers. Such groups have already filed lawsuits against a seller of health foods and hospitals.

Further, under the AMA, anyone (including NGOs) can tip off the JFTC about an alleged infringement of the AMA.

REVIEW OF MERGERS

Thresholds and triggers

12 What are the relevant thresholds for the review of mergers in the pharmaceutical sector?

Share acquisitions, mergers (amalgamations), joint share transfers, business or asset transfers and corporate splits (or demergers) are subject to prior notification under the Antimonopoly Act (AMA) if they exceed certain thresholds. Transactions whose schemes involve more than one of these transactions are separately analysed at each step of the transaction and may require multiple filings. Under the AMA, different notification thresholds apply depending on the different types of transactions.

For share acquisitions, which are most typical, the thresholds are based both on domestic turnover and the level of shareholding in the target. First, the aggregate domestic turnover of all corporations within the combined business group of the acquiring corporation must exceed ¥20 billion, and the aggregate domestic turnover of the target corporation and its subsidiaries must exceed ¥5 billion. Second, such acquisition must result in the acquirer newly holding more than 20 or 50 per cent of the total voting rights of all of the shareholders of the target.

These general rules apply to the pharmaceutical sector.

13 | Is the acquisition of one or more patents or licences subject to merger notification? If so, when would that be the case?

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

Market definition

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

In the *Sankyo/Daiichi* and *Yamanouchi/Fujisawa* merger cases (both in 2005), the Japan Fair Trade Commission (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. The ATC code classifies medical drugs in accordance with the main drug efficacy of the main ingredients. While there are four levels of classification in the ATC code, from level 1 to level 4 (level 4 is the most detailed), the JFTC noted that the product market of medical drugs should generally be defined in accordance with the level 3 classification. While this is the basic method of defining the product market, the JFTC also considers substitutability from the viewpoint of medical institutions and doctors. The *Novartis/GlaxoSmithKline* case of fiscal year 2014 defined such product markets based upon level 4 classification for some products and independently from the ATC code for some other products. The JFTC may be more likely to deviate from the ATC code-based approach when newer types of drugs are at issue.

In the pharmaceutical product sector, geographic markets are generally defined as the market of Japan. In the distribution sector, geographic markets are likely defined as the markets of 47 prefectures.

Sector-specific considerations

15 | 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 some merger cases, the JFTC characterised the market of prescription drugs as an industry where the competitive pressure from the downstream market was intense (*Sankyo/Daiichi*; *Yamanouchi/Fujisawa*). However, in another later 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).

In medical equipment-related mergers, the JFTC did not find there was significant pressure from downstream markets even if negotiation on price was seen, because medical doctors generally prefer medical equipment that they are accustomed to using, rather than new, cheaper equipment (*Abbot Laboratories/St Jude Medical*, 2016; *Zimmer/Biomet*, 2015).

Addressing competition concerns

16 | Can merging parties put forward arguments based on the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

It is unlikely that calling for the strengthening of research and development activities in Japan would be useful in alleviating antitrust concerns. While the Guidelines to Application of the Antimonopoly Act Concerning Review of Business Combination of the JFTC (the Merger Guidelines) refer to efficiency as one of the factors, because the improvement of efficiency must be specific to the merger (ie, should not be one that can be achieved by another method), we are unaware of any merger cases in which efficiency singularly played a significant role in obtaining clearance.

Horizontal mergers

17 | Under which circumstances will a horizontal merger of companies currently active in the same product and geographical markets 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 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.

However, the Merger Guidelines set forth the following safe harbour rules. Horizontal mergers are unlikely to be considered problematic if:

- the Herfindahl-Hirschman 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.

Product overlap

18 | When is an overlap with respect to products that are being developed likely to be problematic? How is potential competition assessed?

When product X that is being developed by a party to a merger is, if launched, expected to become an influential competing product with existing product Y of another party to the merger, and the launch of product X is likely, such overlap between products X and Y may be problematic. In the *Kirin Holdings/Kyowa Hakko* case of 2008, the JFTC cited such overlap involving products under development as one of the reasons why a remedy was required. Further, in the *Novartis/GlaxoSmithKline* case, the JFTC analysed that there was an overlap involving two products to be launched in the near future of one party and two products during Phase III clinical trials of the other party.

Remedies

19 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 require the parties to a merger to divest themselves of overlapping products or assets. Other typical remedies include: allowing competitors access to bottlenecking 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.

However, in Japan, the JFTC has not issued an order of divestiture or any other remedies in merger control for the past approximately 50 years, because almost all merger cases that might invite the interest of the JFTC had been dealt with through an unofficial prior-consultation process with the JFTC up to June 2011, and parties had almost always voluntarily followed the remedy resulting from negotiation with the JFTC, if one was required. While the JFTC effected the abolition of the prior-consultation system on 1 July 2011, all parties to major merger cases since then appear to have negotiated their remedies during Phase II (or sometimes Phase I), and asked the JFTC not to issue an order of divestiture by committing to carry out the agreed remedies. Therefore, it remains unlikely that we will see orders of divestiture in the near future.

ANTICOMPETITIVE AGREEMENTS

Assessment framework

20 What is the general framework for assessing whether an agreement or concerted practice can be considered anticompetitive?

Horizontal agreements and concerted practice are typically analysed in terms of unreasonable restraint of trade among the three types of violations under the Antimonopoly Act (AMA). For hardcore cartel types of horizontal agreements, if the combined market share of the participants to a conspiracy is significant, it is likely that an unreasonable restraint of trade will be found. In the case of horizontal agreements that are not hardcore cartels, the rule-of-reason test will apply.

As concerted practice itself cannot constitute a violation of the AMA, for a concerted practice to be characterised as a violation, a conspiracy (including those that are established after applying a rule-of-reason test) must be established.

Vertical agreements can be categorically ruled out from unreasonable restraint of trade (*In re Asahi Shimbun*, Tokyo High Court judgment, 9 March 1953).

Technology licensing agreements

21 To what extent are technology licensing agreements considered anticompetitive?

The Guidelines for the Use of Intellectual Property under the Antimonopoly Act issued by the Japan Fair Trade Commission (JFTC) on 28 September 2007 (the IP Guidelines; most recently amended on 21 January 2016) set out the extent to which technology licensing agreements are considered to be anticompetitive. Examples of agreements ancillary to technology licence agreements that are, in principle, considered to be anticompetitive are those that:

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

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

- prohibits a licensee from selling or manufacturing competing products; or
- obliges a licensee to pay an amount of royalties, which is not calculated according to the use of licensed technology.

However, according to the IP Guidelines, in principle, it is not considered as unfair trade practice for a licensor to:

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

Co-promotion and co-marketing agreements

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

The anticompetitive effect of co-promotion and co-marketing agreements are evaluated on the basis of a 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 or time-consuming and the relevant pharmaceutical products cannot be sold in Japan without co-promotion or co-marketing. However, such agreements may be considered anticompetitive, because they are in most cases agreements among competitors and may reduce competition between the parties to some extent.

Other agreements

23 What other forms of agreement with a competitor are likely to be an issue? How can these issues be resolved?

An agreement with a competitor is most likely to be deemed anticompetitive if it is characterised as a hardcore cartel. However, 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.

Issues with vertical agreements

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 and restriction on internet sales, which may constitute unfair trade practices (ie, trading on restrictive terms), would most frequently raise antitrust concerns.

In 2020 and 2021, the JFTC approved three applications for approval of a commitment plan submitted by separate contact lens manufacturers, each of which reportedly asked retailers not to display retail prices in advertisements and not to sell contact lenses online to certain users.

Patent dispute settlements

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, either. However, theoretically, 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.

Joint communications and lobbying

26 To what extent can joint communications or lobbying actions be anticompetitive?

In the *Paramount Bed* case (1998), a dominant manufacturer of beds for medical use approached an official of the Tokyo metropolitan government and influenced said government to adopt a specification for beds that contained its IP rights by misrepresenting that the specification somehow could also be reasonably satisfied by its competitors, effectively excluding the business activities of its competitors. The JFTC held that the activities of Paramount Bed Co, Ltd constituted private monopolisation (exclusionary type).

Public communications

27 To what extent may public communications constitute an infringement?

Under the AMA, conscious parallelism is not a violation. As such, even if company A makes a press statement to raise a price and companies B and C follow suit, unless and until a conspiracy that falls under unreasonable restraint of trade is found, no infringement will be found. However, a conspiracy is not limited to only explicit conspiracy, but also includes implicit conspiracy.

Exchange of information

28 Are anticompetitive exchanges of information more likely to occur in the pharmaceutical sector given the increased transparency imposed by measures such as disclosure of relationships with HCPs, clinical trials, etc?

Consistent with similar initiatives in other jurisdictions, a number of trade associations (including the JGA and the JPMA) have published guidelines on transparency with regard to the relationship between pharmaceutical companies and medical institutions. Similarly, certain information on ongoing clinical trials is available at various sources, including the Ministry of Health, Labour and Welfare website. However, we are unaware of any influential arguments that such initiatives for transparency have increased the likelihood of anticompetitive exchanges of information. Conscious parallelism is not a violation of the AMA.

ANTICOMPETITIVE UNILATERAL CONDUCT

Abuse of dominance

29 In what circumstances is conduct considered to be anticompetitive if carried out by a firm with monopoly or market power?

The Antimonopoly Act (AMA) does not explicitly 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. There are two types of conduct that may be deemed private monopolisation: exclusion of competitors and controlling of competitors.

Anticompetitive 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 Japan Fair Trade Commission (JFTC) and the activity tends to impede fair competition.

Owing to the difference in the required level of restriction on competition between private monopolisation and unfair trade practices and most activities of private monopolisation overlapping with those of unfair trade practices, private monopolisation has only been enforced in a very limited number of cases.

De minimis thresholds

30 Is there any de minimis threshold for a conduct to be found abusive?

The situation in Japan is far from being consistent with the concept of de minimis threshold. First of all, the AMA does not refer to any de minimis threshold. In addition, for unfair trade practice, the degree of anticompetitiveness is considered low. Further, in terms of abuse of superior bargaining position, which is one category of unfair trade practice, a superior bargaining position is found if a party's position is stronger than the other party, without any reference to the first party's market share or turnover.

Market definition

31 Do antitrust authorities approach market definition in the context of unilateral conduct in the same way as in mergers? If not, what are the main differences and what justifies them?

The short answer is no. First of all, in the case of certain types of unfair trade practices, the JFTC's position is that market definition is not necessary.

The Guidelines for Exclusionary Private Monopolisation under the Antimonopoly Act, issued by the JFTC on 28 October 2009 (the EPM Guidelines), state that the JFTC will 'assess the scope influenced by the related trade depending on factors such as the objects, regions, and conditions of the conduct and trade and determine the scope where competition is substantially restrained', while it could secondarily consider the substitutability, which plays the central role in merger case.

Establishing dominance

32 When is a party likely to be considered dominant or jointly dominant? Can a patent owner be dominant simply on account of the patent that it owns?

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 EPM Guidelines 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 a market share of more than 50 per cent will likely be considered dominant in the context of exclusionary or control types of private monopolisation and should use more caution than other companies.

IP rights

33 To what extent can an application for the grant or enforcement of a patent or any other IP right (SPC, etc) 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, 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. In 2000, the JFTC issued a recommendation decision (which is similar to a consent decree) 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, 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, as well as exercising certain facets of a standard essential patent (like seeking an injunction against those who are willing to obtain a licence after a 'fair, reasonable, and non-discriminatory' declaration), could violate the AMA.

34 When would life-cycle management strategies expose a patent owner to antitrust liability?

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 to delay the entry of a generic drug, on the ground that conducting tests necessary for an application of product-specific approval, under article 14 of the then-current Act 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 grounds that there is an infringement of patents related to the manufacturing method, whose application was filed later than the one for substance patent).

Communications

35 Can communications or recommendations aimed at the public, HCPs or health authorities trigger antitrust liability?

While recommendation of a product would be unlikely to trigger antitrust liability, defaming products of competitors may give rise to antitrust liability. In the *Daiichikosho* case (2009), the IP holder's refusal to grant a licence for certain popular tunes to a competitor in the karaoke machine industry, followed by spreading notices to the effect that the competitor's karaoke machines will not be able play those popular tunes, was found to be 'interference with a competitor's transactions'. Foreign companies may also bear in mind that comparative advertisement is not widely seen in Japan; as such, any marketing activity that potentially involves downplaying a competitor's products or services may easily draw the attention of the regulators.

Separately, overaggressive claims may result in violation of the PRA and the Act.

Authorised generics

36 Can a patent owner market or license its drug as an authorised generic, or allow a third party to do so, before the expiry of the patent protection on the drug concerned, to gain a head start on the competition?

Yes, it is possible. The first authorised generic in Japan was launched in 2013. Such practice is not commonly seen in Japan, because the launch of an authorised generic generally results in a considerable decrease in the price of drugs at the most downstream level calculated according to a notification of the Ministry of Health, Labour and Welfare, which has the effect of pushing down the prices at which drug manufacturers sell their drugs at upstream level.

Restrictions on off-label use

37 Can actions taken by a patent owner to limit off-label use trigger antitrust liability?

To the extent a patent holder's restriction on off-label use is unreasonable, it may fall under 'trading on restrictive terms', one category of unfair trade practices. However, as the health insurance system is not applicable to off-label use and, at least generally, off-label use comes with higher risks, it is unlikely that such restriction will ultimately be found to be unreasonable. Moreover, as the JFTC is unlikely to be the governmental authority that is best suited to determine the 'reasonableness' of restriction on off-label use, we do not believe that there will be any JFTC enforcement against such restrictions in the near future.

Pricing

38 When does pricing conduct raise antitrust risks? Can high prices be abusive?

As the prices of medical drugs are highly regulated in Japan (at least at the most downstream level), it is unlikely that any pharmaceutical company would try to set high prices that may be challenged under the AMA. While over-the-counter (OTC) drugs are not subject to regulatory control, it is unlikely that demand for a particular OTC drug is so high that sellers thereof would try to set abusively high prices.

Sector-specific issues

39 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 certain consultation cases, 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.

UPDATES AND TRENDS

Recent developments

40 Are there in your jurisdiction any emerging trends or hot topics regarding antitrust regulation and enforcement in the pharmaceutical sector?

In light of the following developments, we are of the view that the healthcare industry must exercise more caution than ever before to avoid infringing antitrust rules:

- on 4 June 2019, the Japan Fair Trade Commission (JFTC) issued a cease-and-desist order and surcharge payment order against Koa Isei Co, Ltd (a generic drug manufacturer) after finding a price-fixing cartel involving an anti-hyperphosphatemia drug;
- on 24 October 2019, the JFTC published the results of its review of a merger between M3 Inc (an operator of a platform business to offer medical drug-related information) and Nippon Ultmarc Inc (a manager of a database of medical information), which was unique in that (1) the JFTC reviewed the merger ex post facto because the merger did not meet the filing threshold; and (2) the parties had to agree to considerable remedies;
- on 27 November 2019, the JFTC raided four large drug wholesalers on the allegation of bid-rigging involving medical drugs centrally procured by JCHO, an incorporated administrative agency;
- on 9 December 2020, the JFTC requested that the Public Prosecutors' Office bring charges against three drug wholesalers in the JCHO case; and
- effective 1 August 2021, a surcharge will be imposed on companies that make false or exaggerated representations in advertisements relating to pharmaceuticals and cosmetics products or medical equipment.

Coronavirus

41 What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

Often, Japanese companies that have a strong bargaining position will abuse their power and exploit other Japanese companies that are in a weaker position. In an effort to rectify this practice, the Japan Fair Trade Commission (JFTC) has been authorised to take action against violations of the Anti-Monopoly Act, which prohibits unfair trade practices such as 'abuse of a superior bargaining position' and 'tie-in sales,' and violations of the Subcontract Act, which prohibits certain exploitative acts and conduct that tends to result in exploitation. Concerned that these violations may increase as a result of the pandemic, the JFTC published a number of announcements and guidance documents beginning in February 2021 that are intended to prevent violations and to clarify acceptable conduct.

The JFTC further published FAQs regarding collaboration among competitors in order to address difficulties arising from the pandemic.

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