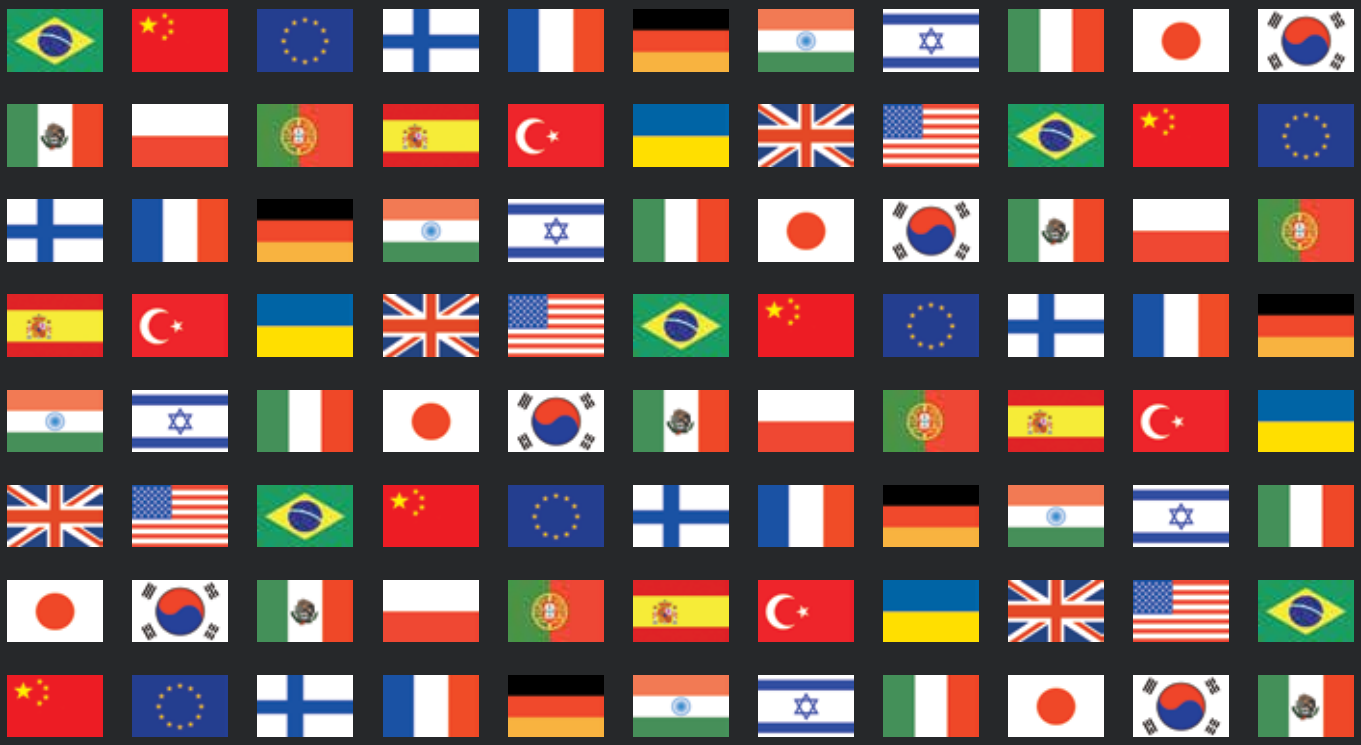
Pharmaceutical Antitrust

Contributing editors
Marta Giner Asins and Yann Anselin



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GETTING THE DEAL THROUGH

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Pharmaceutical Antitrust 2017

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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? Which bodies are entrusted with enforcing these rules?

The primary piece of legislation setting out the regulatory framework for the marketing and authorisation 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 name of which was changed from the Pharmaceutical Affairs Act as of 27 November 2014.

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). Prices of over-the-counter (OTC) drugs are not subject to the notification. This chapter focuses primarily on drugs covered by public health insurance.

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

2 Is there specific legislation on the distribution of pharmaceutical products?

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

3 Which aspects of this legislation 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. 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

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). Based on article 3 of the PRA, the Japan Fair Trade Commission (JFTC) has issued a notice on the Restriction on the Provision of Premiums in Medical Drug Business, Medical Equipment Business and Sanitary Survey Business (Notice No. 54 of 1997).

5 Which authorities investigate and decide on pharmaceutical mergers and the anticompetitive nature of conduct or agreements in the pharmaceutical sector?

The JFTC is the main competition agency in Japan, and it investigates and decides antitrust issues in the pharmaceutical sector, as well as in any other field, unless a criminal case is initiated. 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.

6 What remedies can competition authorities impose for anticompetitive 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 Secretary General of the CAA can impose cease-and-desist orders on the violation of the PRA, and effective 1 April 2016, the Secretary General of the CAA can also issue orders for the payment of surcharges on certain types of violations of the PRA (see 'Update and trends').

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 such criminal cases usually does not exceed one per year.

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

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive 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, as a result of 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 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 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).

8 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 2015, the JFTC and Competition Policy Research Center (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. The JFTC conducted a number of interviews with pharmaceutical companies operating in Japan during the project. In their final report issued in 2015, they concluded that while the market structure in Japan makes it less likely for 'reverse payment' settlements to be prevalent, the JFTC should monitor the market practices continuously.

Please note that the above-mentioned practice of the JFTC is quite different from what is called a 'sector inquiry' in Europe, in that responses are optional and the JFTC can only provide analysis or proposals, but not take formal actions, based on the results of such inquiries.

9 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, 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). In relation to this, on 21 January 2015, the Kyoto District Court ordered the enjoinment of certain forms of representation and distribution of advertisements of chlorella products by a seller of health foods by holding that, in seeing the representation, consumers are likely to misunderstand that the product has been approved as medicine under the Act, which is not the case in reality. However, the Osaka High Court overturned it on 25 February 2016 as the defendant had already ceased the advertisements, and this was ultimately supported by the Supreme Court on 24 January 2017. This case was initiated by a consumer organisation that is not focused on the pharmaceutical sector, but rather on general consumer affairs.

Review of mergers

10 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 the JFTC's recognition of the features of the prescription drug market.

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

In both the *Sankyo/Daiichi* and *Yamanouchi/Fujisawa* merger cases (see question 10), 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. 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 classification), 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. The *Novartis/GlaxoSmithKline* case of fiscal year 2014 defined such product markets based upon level 4 classification and independently from the ATC code.

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

12 Is it possible to invoke before the authorities 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, which were most recently amended effective as of 1 July 2011 (the Merger Guidelines), refers 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 plays a significant role in obtaining clearance.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market 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 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-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.

In addition, the JFTC is unlikely to conclude that transactions falling within the following threshold would substantially restrain competition in any particular market: the HHI after the notified transaction is not more than 2,500, and the merging parties' market share is not more than 35 per cent.

14 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 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 10), the JFTC cited such overlap involving products under development as one of the reasons why the merger between the parties should come with a remedy. Further, in the *Novartis/GlaxoSmithKline* case (see

question 11), 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.

15 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.

Please note, however, that in Japan the JFTC has not issued an order of divestiture or any other remedies in merger control for the last 45 years, because almost all merger cases that might invite the interest of the JFTC have been dealt with through an unofficial prior-consultation process with the JFTC until June 2011, and parties have almost always voluntarily followed the remedy resulting from negotiation with the JFTC, if one is required. While the JFTC abolished the prior-consultation system effective as of 1 July 2011, all parties to major merger cases since then appear to have negotiated their remedies during Phase II, and asked the JFTC not to issue an order of divestiture by agreeing to carry out the agreed remedies. Therefore, it remains unlikely that we will see orders of divestiture in the near future.

16 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.

Anticompetitive agreements

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

In general, 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 24). 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.

18 To what extent are technology licensing agreements considered anticompetitive?

The Guidelines for the Use of Intellectual Property under the Antimonopoly Act issued by the JFTC on 28 September 2007 (the IP Guidelines; most recently amended on 21 January 2016) set out to what extent 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;
- 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 anticompetitive ancillary agreements, agreements that are considered anticompetitive to the extent that their effect may be to impede fair competition 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.

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

The anticompetitive effect of co-promotion and co-marketing agreements will be 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 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 anticompetitive, because they are in most cases agreements among competitors and may reduce competition between the parties to some extent.

Where the combined market share of parties to such co-promotion or co-marketing agreements is large and the parties want to reduce the risk of such agreements being considered anticompetitive, it would be advisable not to prohibit them from promoting or marketing the products through their own distribution channels.

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.

20 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 anticompetitive 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.

21 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 retailers that Eisai's vitamin E products be sold at the retail price stipulated by

Update and trends

On 14 February 2017, the CAA announced that it issued a cease-and-desist order to Nippon-supplement Inc. Based upon the finding that the infringement survived 1 April 2016 (effective date of the amendment to the PRA to introduce surcharges; see question 6), this will likely result in the first-ever order for the payment of surcharges against a health food company under the PRA. Any company dealing with health foods or pharmaceutical products (including medical drugs) should be alerted to this case and is encouraged to regularly monitor any products due to be shipped, even after successfully obtaining regulatory approvals.

Under Japanese law, after undergoing review and obtaining approval from the Secretary of the CAA, certain health foods may be labelled and characterised as 'foods for specified health uses' (*tokuho*). Given the wide recognition of the *tokuho* logo among Japanese consumers, it is considered important for many health food makers to obtain and maintain *tokuho* for its health foods. While Nippon-supplement Inc obtained such approval as to its peptide products and fermented soy beans products, its recently shipped products failed to meet the representations that were described on the label as part of the *tokuho* claim. Apparently frustrated by this case, the CAA, in addition to imposing a cease-and-desist order, went on to announce in the same press release that it would deal strictly with any future similar cases and continue monitoring (including buying up products from the market on an anonymous basis) and conducting regular audits.

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.

22 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 (see question 17). The JFTC published 'Competition in the Pharmaceutical Market and Incentives for Research and Development – through Review of Effects of Entry of Generic Drugs into the Market' on 7 October 2015, alerting pharmaceutical companies in Japan to the issue of reverse payments, and is believed to be continuously monitoring market practices with interest (see question 8).

23 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 (see question 9)) 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 MHLW website. However, we are unaware of any influential arguments that such initiatives for transparency have increased the likelihood of anticompetitive exchanges of information. Please note that conscious parallelism is not a violation of the AMA.

Anticompetitive unilateral conduct

24 In what circumstances is conduct considered to be anticompetitive 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 question 25). 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.

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 JFTC. Under unfair trade practices, a firm will be held liable if it commits one of these activities and the activity tends to impede fair competition (see question 17).

It is generally thought that a 'substantial restraint of trade' (the standard under private monopolisation) requires a higher degree of anticompetitiveness 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 anticompetitiveness than unfair trade practices) has only been enforced in a very limited number of cases.

25 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 or control types of private monopolisation and should use more caution than other companies.

26 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 would be unlikely to 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.

27 To what extent can an application for the grant or enforcement 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 (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 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, 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 FRAND declaration), could violate the AMA.

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 anticompetitive 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 anticompetitive 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 of using them, and then refuses to issue a licence.

28 Can certain life-cycle management strategies also expose the 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 in order to delay the entry of a generic drug, on the grounds 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).

29 May a patent holder 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 calculated according to a notification of the MHLW (see question 1), which has the effect of pushing down the prices at which drug manufacturers sell their drugs.

30 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 20, 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 certain categories of collaboration among competitors and vertical restraints (those that are subject to rule-of-reason review) and merger clearances.

31 Has national enforcement activity in relation to life cycle management and settlement agreements with generics increased following the EU Sector Inquiry?

Not applicable.

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