

Pharmaceutical Antitrust

The application of competition regulation
in 29 jurisdictions worldwide

2009

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Korea

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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 regulatory framework governing the marketing approval for pharmaceutical products as well as their manufacture, importation, and distribution generally, is found in the Pharmaceutical Affairs Law and related regulations (PAL), while the pricing of pharmaceutical products is regulated under the National Health Insurance Act and related regulations (NHIA).

In addition, the legality of promotional activities in the pharmaceutical sector is governed by the anti-bribery provisions of the Korean Criminal Code, fair trade provisions under the Monopoly Regulation and Fair Trade Law (FTL), and certain gift-giving provisions under the PAL.

- 2 Which bodies are entrusted with enforcing these regulatory rules?

The Korea Food and Drug Administration (KFDA) enforces the PAL, while the Ministry for Health, Welfare and Family Affairs oversees and enforces the NHIA. The Korean Criminal Code is generally enforced by the Prosecutor's Office, while the Korea Fair Trade Commission (KFTC) enforces the FTL.

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

Of the above-cited legislation, the FTL is the principal body of competition law in Korea, which is relevant to all sectors of industry, including the pharmaceutical sector.

Competition legislation and regulation

- 4 Which legislation sets out competition law?

The primary antitrust and competition law in Korea is the FTL. The FTL regulates various aspects of competitive behaviour, including the following general areas of activity:

- monopolies, monopolisation and abuse of monopolistic power in general;
- business combinations, including mergers and acquisitions;
- unfair collaborative activity; and
- unfair trade practices.

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

The KFTC has not issued any fair competition guidelines specifically for the pharmaceutical sector. However, it has reviewed and approved

a number of voluntary industry codes governing promotional activities in the pharmaceutical sector, which have been adopted by industry associations and have the force of government regulation by virtue of their having been approved by the KFTC. They are the Voluntary Code for Fair Competition in the Sale of Pharmaceutical Products adopted by the Korean Pharmaceutical Manufacturers Association (KPMA); the Fair Competition Code and its Working Guidelines; and the Voluntary Code on Labelling and Advertising for Drugs, both adopted by the Korea Research-Based Pharmaceutical Industry Association (KRPIA).

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

The KFTC is the relevant authority responsible for investigating and determining anti-competitive effects of mergers and other conduct across all sectors of industry in Korea, including the pharmaceutical sector.

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

If the KFTC determines that there is a violation of the FTL, it is authorised to impose the following sanctions: issue a corrective order demanding that the offending party or parties immediately cease all prohibited activity; require publication of a formal announcement of the violation in accordance with specifications; or require payment of penalties. For serious violations, the KFTC may refer the case to the prosecutors. These sanctions apply to all violations, regardless of industry.

- 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 principle, depending on the type of violation, private remedies are available under the FTL for parties who suffer harm from anti-competitive conduct or agreements, regardless of industry, in the form of injunctive relief or compensatory damages. However, such remedies are limited to compensatory damages to the extent of the actual damages caused by the violating conduct, as Korean courts do not recognise the concept of punitive damages generally. For this reason, claims for damages based on violation of the FTL are rare. Injured private parties tend to seek recourse by filing complaints with the KFTC, rather than initiating individual lawsuits against the offending party or parties.

- 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?

The KFTC is authorised to conduct sector-wide inquiries at its discretion and has, in fact, conducted sector-wide investigations every few years into possible antitrust or fair-trade law violations, focusing primarily on whether pharmaceutical companies are engaged in promotional or marketing activities that constitute unfair solicitation of business. The most recent sector-wide investigation into fair-trade law violations started in October 2006, with the KFTC deciding on the first group of 10 companies to be investigated (mostly domestic) issued in November 2007 and on the second group of seven companies (mostly multinational drug companies) on January 2009. Of the first group of 10 companies, all were subject to administrative fines and five of them were referred to the prosecutors for criminal investigation, which resulted in a finding of violation. As to the second group of seven companies, all were subject to administrative fines but none was referred to the prosecutors for criminal investigation.

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

Aside from competition laws enforced by the KFTC, the KFDA may also promulgate laws and regulations governing the pharmaceutical sector. However, apart from regulations regarding promotional activity and advertising, the KFDA generally has not ventured into those areas that are regulated by the KFTC. As to promotional activities, the KFDA issued new regulations under the PAL, effective 14 December 2008, that provide express grounds for the KFDA to impose administrative sanctions on pharmaceutical companies for providing ‘economic benefits, including monies, goods, conveniences, services and entertainment, to healthcare professionals, medical institutions or pharmacies for the purpose of promoting the sale of pharmaceutical products’. Because the language of the new regulation is very broad in scope, one could argue that the amendment allows the KFDA to impose sanctions for practices that are considered routine and acceptable in many countries. However, because the amendment above is very recent, it is hard to say how strictly the KFDA will interpret and enforce the new regulations. There are no clear cut legal or policy mechanisms to avoid conflicting exercise of jurisdiction or to make application of the PAL regulation and competition regulation consistent.

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

In certain areas, antitrust concerns can be addressed with industrial-policy arguments in Korea. For example, in the area of merger approval, even where a merger is deemed likely to have an anti-competitive effect, the KFTC can approve it if:

- the gains from efficiency resulting from the merger will outweigh the costs of the anti-competitive effects of the merger or
- one of the parties to be merged is a non-viable, failing company as defined in FTL regulations.

To determine whether potential efficiency gains will justify approving the merger, the KFTC looks to the potential for gains in production, sales, and R&D capability or efficiency gains for the Korean economy as a whole.

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

There are several non-government organisations and associations that address competition concerns relating to the pharmaceutical sector, such as the KPMA and the KRPIA, but their concerns relate more to unfair trade practices rather than other areas of competition law, such as cartel, market dominant position, and mergers. There are also consumer rights groups and patient groups whose focus does not include antitrust concerns per se but whose work in the areas of public health and consumer rights advocacy may raise or impact on antitrust issues.

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?

The sector-specific features of the pharmaceutical industry – in particular the high degree of regulation as to entry of new products and rules for determining and adjusting the reimbursement prices of drugs – figure prominently in the KFTC’s review of merger applications. To assess whether a given merger is likely to have an anti-competitive effect, the KFTC first defines the relevant product market and geographic market and then reviews the respective market shares of the parties and other competitors, the historical trend of the market shares, and such other factors as the possibility of new market entry including imports, the existence of substitutes for the products of the companies undergoing merger, and the possibility of collusion among competing companies after the merger. The KFTC examines the sector-specific features of the pharmaceutical industry to the extent that they heavily affect the analysis of the above factors.

We note that Korean merger rules have extraterritorial application, which means that overseas mergers between foreign entities that are likely to have an impact on the Korean market will need to be approved in Korea by the KFTC if they meet the numerical thresholds for filing.

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

In principle, the product market and geographic market are defined under FTL regulations as the market where a hypothetical monopolist can increase the price by SSNIP (small but significant non-transitory increase in price) without losing profit. In practice, the KFTC tends to determine the product market by referring first to the third level of classification (chemical/pharmacological subgroup), also referred to as ‘ATC-3’, under the Anatomical Therapeutic Chemical (ATC) classification system.

The KFTC tends to take the domestic market – Korea – as the relevant geographic market for the pharmaceutical sector.

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

First, the presumption of anti-competitive effect will arise if the following conditions are met:

- either the combined company will hold 50 per cent or more of market share, or the top three companies (with the combined company as one of them) hold 75 per cent or more of market share;
- the combined market share is the largest in the market; and
- the combined market share exceeds that of the second market shareholder by not less than 25 per cent of the combined market share.

In practice, if the above conditions are met in any product category (usually defined at the ATC-3 level), the presumption of anti-competitive effect will arise, and the burden will be on the applicants to rebut this presumption. However, this presumption is intended as the first step of a broader analysis of anti-competitive effect taking into account the factors mentioned in question 13.

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

In general, the KFTC has not tended to consider pipeline products in its examination and review of pharmaceutical mergers.

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

In general, when the KFTC determines there are issues with a particular merger, it may decline to approve the merger altogether, or in the alternative, issue conditional approval requiring, for example, the spinning off of a part of the business of the combined company, a cap on market share, or the sale of specific assets. Where the KFTC determines that a merger between pharmaceutical companies may be anti-competitive as to one or more product categories, the KFTC is likely to order the sale of the products, and the sale would relate only to the Korean market.

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?

Under merger review guidelines, the acquisition of one or more patents or licenses alone, without other assets, could, in principle, require antitrust approval if they constitute all or an important part of the business of another company or all or 'an important portion' of the fixed assets for a business. An 'important portion of the business' is deemed to be acquired if the purchase price is 10 per cent or more of the transferor company's total assets as stated in the financial statement of the most recent fiscal year, or 5 billion Korean won or more. Since patents and licences do qualify as the fixed assets of business, the acquisition of one or more patents or licence would require a merger filing if this numerical threshold is met.

Anti-competitive agreements

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

As mentioned above, the KFTC focuses on the following three areas of scrutiny to assess the anti-competitiveness of an agreement or practice: monopolies, monopolisation and abuse of monopolistic power in general; unfair collaborative activities; and unfair trade practices. We discuss the general framework for analysing the anti-competitiveness of typical agreements in the pharmaceutical sector below.

20 Have there been cartel investigations in the pharmaceutical sector?

Cartel investigations into the pharmaceutical sector are rare; we are aware of only one cartel investigation into the pharmaceutical sector, which related to the supply of vaccines to public hospitals. We believe this is mainly because the prices of drugs that are reimbursed under Korea's national health insurance system (which covers a great majority of prescription drugs) are set by the government under set formulas, which means there is effectively no room for price fixing. Where there is potential for cartels, in terms of agreement on such factors as production, sales and territorial allocation, is through co-promotion agreements, but this has not been an active area of KFTC scrutiny, although it is likely to become more of an issue in the near future.

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

The KFTC may consider a technology licensing agreement anti-competitive to the extent it contains terms that may, when viewed in the totality of the circumstances, constitute unfair trade practices. Such terms include, for example, fixing the price at which the licensee should sell the product in question and imposing restrictions on such features as the sourcing of raw materials, production quantities, exportation, and on territories of sale or customers within Korea.

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

Although numerous instances of co-promotion and co-marketing arrangements exist among pharmaceutical companies, the KFTC has not specifically examined the legality of such practices in Korea to date. However, the KFTC recently published the results of a study that it commissioned on the potential for co-promotion and co-marketing agreements to have anti-competitive effects, which, along with recent announcements, indicate that this is likely to be a new, major focus of KFTC scrutiny in the pharmaceutical sector. According to this study, the potential for violation of the FTL exists to the extent the agreements include territorial or customer allocation, exclusive dealing, imposing minimum sales targets, and resale price maintenance.

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

See questions 20 to 22. While confidentiality provisions may reduce the likelihood of the agreements coming to the attention of the KFTC, they will not resolve the underlying issue of whether there is collusive activity.

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

In vertical agreements, such as a distribution agreement, the aspects most likely to raise antitrust concerns are resale price maintenance, ie, requiring the distributor to resell the product to its customers at a set price, minimum purchase or sales targets, requiring the distributor to distribute exclusively the supplier's product without granting a reciprocal, exclusive distribution right for the same product, and restrictions on sales in terms of geographical area or customers.

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

Unlike in the US where settlement of patent disputes must be reported to the antitrust authorities, there is no such reporting requirement in Korea at this time. And, as mentioned above, there is as yet no court precedent or KFTC decision on this issue. However, the KFTC is aware of recent US cases in which patent owners were found in violation and sanctioned for compensating generic makers in exchange for delaying market entry for a set period of time (see question 29). Accordingly, we believe there is a high risk that a settlement of a patent dispute will expose the parties to liability for an antitrust violation. Settlement for the purposes of finding liability could include more indirect ways, such as through the granting of distribution and marketing rights or licensing arrangements under highly favourable terms.

Update and trends

The KFTC is paying greater attention to the issue of enforcement as regards the abuse of intellectual property rights (IPR). In the KFTC Work Plan for 2009 issued in December 2008, the KFTC identified one of its four major objectives for 2009 as enforcing Korean competition law in line with international trends, and, specifically, strengthening enforcement to prevent the abuse of IPRs, particularly in the pharmaceutical and IT sectors. The KFTC has been closely following enforcement in this area in both the US and the EU; it

is noteworthy, for example, that the highly publicised preliminary findings of a study by the EU into the state of competition in the pharmaceutical industry published in November 2008 also received much attention in Korea. Currently, there is no KFTC decision or Supreme Court precedent in this area. Accordingly, in pursuing enforcement in this area, the KFTC is likely to review how the US and the EU have handled abuse of IPRs by the pharmaceutical industry for benchmarking purposes.

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?

Under the FTL, if a company enjoys a market dominant position in a particular market, the KFTC will apply heightened scrutiny to the company's activities. In particular, market dominant companies will be prohibited from actions that, in the totality of circumstances, constitute unreasonably fixing, maintaining or changing the price of a good or services fees, controlling the sale of goods or rendering of services, interrupting the business activities of others, interfering in the entry of new competitors, and eliminating competitors.

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

A party is deemed to enjoy market dominance if it has 50 per cent or more of the market share in the relevant market, or if it is one of three market share leaders where the total aggregate market share of the three market share leaders is greater than a 75 per cent share of the relevant market.

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

Whether a company enjoys a market dominant position is determined by the actual market share that company enjoys and as such, merely holding a patent to a pharmaceutical product without actual sale and resulting market share would not render that company a market dominant player.

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

See questions 30 and 31.

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

This is difficult to address, as there is no court precedent or KFTC decision in this area. However, there are certain FTL provisions under which certain activities of original developers to enforce their patents rights may be found in violation of the FTL. First, the KFTC provides in its guidelines on the criteria for determining abuse of dominant market position that a patent holder could be found to be abusing its market dominant position if it brings an infringement action knowing that the other party's acts do not infringe upon its patent. Other relevant fair trade law provisions may include the prohibition on business interference and other forms of abuse of market dominant position. In this context, it is noteworthy that a KFTC official recently stated at an indus-

try-sponsored conference that abuse of patent litigations or other abusive acts by patent holders would be subject to strict enforcement of the FTL, adding that if the patent holder delays the entry of a generic into the market by means of collusive acts with the generic manufacturer, such acts may constitute illegal cartel activity prohibited by the FTL.

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

This is uncertain, as we are not aware of any KFTC decision or court precedent on the issue. However, mounting criticism by consumer protection groups and regulators in Korea over so-called 'evergreening' of patents and efforts by patent holders to protect their patent position could lead to increased scrutiny by the KFTC. Pressure in Korea for drug patent holders to protect their patent protections is high; the absence in Korea of a link between the drug patent system and the drug registration and approval system means that generic makers can and do apply for product registration sometimes far in advance of the original's patent expiration in order to secure a favourable pricing position (the first of the generics to register enjoy higher pricing). At the same time, the first entry of a generic into the Korean market will result in a 20 per cent cut in the reimbursement price of the patent-protected original drug. Accordingly, defending the patent and the reimbursement price has become an important part of the life-cycle management of patented drugs.

- 32 Do authorised generics raise issues under the competition law?

To date, the KFTC has not taken issue with the potential anti-competitive impact of co-marketing arrangements, whereby a patent holder licenses a generics company to produce and sell a generic version of a brand name product, in effect creating an 'authorised generic' product that enjoys the same original drug reimbursement pricing (see question 22). However, given the recent attention that the KFTC has paid to the issue of co-promotion and co-marketing generally, we cannot rule out that the KFTC may change its stance on this issue.

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

This issue is difficult to address, as there have been few KFTC findings of violation of antitrust law in the pharmaceutical sector to date. However, one of the few cases that does exist, involving resale price maintenance, suggests that the specific features of the pharmaceutical sector are not likely to go far in providing an objective justification for conduct that would otherwise be infringing antitrust

rules. In that case, companies argued that they were forced to require distributors or wholesalers to sell their pharmaceutical products at a specific price, because of reimbursement rules that allow regulators to reduce reimbursement prices of drugs if the regulators find

through surveys that wholesalers or distributors have supplied the drugs in question to hospitals, clinics or pharmacies at prices lower than the reimbursement prices for the drugs. The KFTC rejected these arguments.

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