GETTING THE DEAL THROUGH

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Turkey

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Pharmaceutical regulatory law

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

The primary legislation for the marketing, authorisation and pricing of pharmaceutical products is Law No. 1262 on Pharmacies and Pharmaceuticals, which dates way back to 1928. Law No. 3359 on the Basic Health Services is also relevant to this matter. These statutes provide a basic regulatory framework and leave the details for regulation up to the secondary legislation.

Marketing/Licensing

The main secondary legislation on the licensing of pharmaceuticals is the Licensing Regulation of Pharmaceutical Products (Official Gazette of 19 January 2005, No. 25705). This regulation is akin to and closely modelled after the Directive 2001/83/EC of 6 November 2001 on the Community Code relating to Pharmaceutical Products for Human Use.

Conditions of licensing of the variations in the licensed or to-be-licensed pharmaceuticals are laid down in the Regulation on Variation in the License Application Pending Products (Official Gazette of 23 May 2005, No. 25823). This regulation, in turn, is closely modelled on the Commission Regulation (EC) No. 1084/2003 of 3 June 2003.

The Turkish licensing regulations seek two separate licences for the licensing and marketing of pharmaceuticals. The provider of the licences is the Ministry of Health.

Pricing

The pricing of pharmaceuticals is regulated by the Decree on the Pricing of Pharmaceutical Products (Official Gazette of 22 September 2007, No. 26651). The Ministry of Health uses its powers under the legislation to issue and circulate pricing communiqués from time to time. These communiqués lay down the ever-changing details of the pricing regime.

Turkey applies a reference pricing system in which the lowest ex-factory prices in certain reference countries serve as a benchmark for the ex-factory price of the original and generic pharmaceuticals. Profit margins in the different levels or layers of the distribution chain are strictly controlled. The reference countries have currently been selected as France, Greece, Italy, Portugal and Spain. The base price of original products with no generics in the Turkish market cannot exceed the lowest reference country price, whereas the base price of original products with generics cannot exceed 66 per cent of the lowest reference country price. The ex-factory price of generics cannot exceed 66 per cent of the lowest reference country price.

Once the ex-factory base price (ie, price to the wholesaler) has been set, profit margins are added at each level of the distribution chain. Profit margins of wholesalers range between 2 and 9 per cent, depending on the value of the product. Pharmacies' margins range between 12 and 25 per cent.

Promotion/Sale

Rules of the promotion and marketing of pharmaceuticals are laid down in the Regulation on Promotion Activities for Human Medical Products (Official Gazette of 23 October 2003, No. 25268). This regulation follows the generally applicable business ethics rules concerning the promotion and advertisement of pharmaceuticals.

2 Which bodies are entrusted with enforcing these regulatory rules?

The regulatory rules for the licensing, pricing and marketing of pharmaceutical products are enforced by the Ministry of Health. The General Directorate of Pharmaceuticals and Pharmacy, a subdirectorate of the Ministry, is specifically tasked with enforcing these rules.

Antitrust rules for the industry are enforced by the Turkish Competition Authority, as explained below.

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

Aside from the price and profit margin ceilings, the regulatory framework for pharmaceutical products is not specific or directly relevant to the application of Turkish competition laws to the pharmaceutical industry. The industry is subject to the general competition law rules.

Competition legislation and regulation

4 Which legislation sets out competition law?

The relevant legislation setting out competition law is Law No. 4054 on the Protection of Competition enacted on 13 December 1994 (Competition Law).

The national competition authority for enforcing the Competition Law in Turkey is the Turkish Competition Authority (Authority), a body with administrative and financial autonomy.

To supplement the antitrust enforcement, the Authority has issued communiqués, regulations and guidelines as secondary legislation. The following is a list of all communiqués currently in force: Communiqué No. 2010/4 on Mergers and Acquisitions that Require the Approval of the Competition Board, Communiqué No. 2010/2 on Hearings Held vis-à-vis the Competition Board, Communiqué No. 2010/3 on the Regulation of the Right of Access to the File and Protection of Trade Secrets, Block Exemption Communiqué No. 2008/2 on Technology Transfer Agreements, Block Exemption Communiqué No. 2008/3 in Relation to the Insurance Sector, Block Exemption Communiqué No. 2005/4 on Vertical Agreements and Concerted Practices in the Motor Vehicle Sector, Block Exemption Communiqué No. 2003/2 on Research and Development Agreements, Block Exemption Communiqué No. 2002/2 on Vertical Agreements, Communiqué No. 1998/3 on the Procedures and Principles to be Pursued in Pre-Notifications and Authorisation Applications to be Filed with the Competition Authority in order for Acquisitions via Privatisation to Become Legally Valid,

Communiqué No. 1997/5 on the Conclusion of the Organisation of the Competition Authority.

The following is a list of all the guidelines currently in effect: Guidelines on Remedies That Are Acceptable by the Turkish Competition Authority in Merger/Acquisition Transactions, Guidelines On Undertakings Concerned, Turnover And Ancillary Restraints In Mergers And Acquisitions, Guidelines on the Definition of Relevant Market, Guidelines on Certain Toll Manufacturing Agreements Between Non-Competitors, Guidelines on the Voluntary Notification of Agreements, Concerted Practices and Decisions of Associations of Undertakings, Guidelines on the Explanation of the Block Exemption Communiqué on Vertical Agreements.

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

There are no guidelines that are directly relevant to the pharmaceutical sector. Depending on each individual case, any of the communiqués and regulations may apply to the pharmaceutical sector. In particular, Block Exemption Communiqué No. 2002/2 on Vertical Agreements (Communiqué No. 2002/2), Block Exemption Communiqué No. 2008/2 on Technology Transfer Agreements (Communiqué No. 2008/2), Guidelines on Certain Toll Manufacturing Agreements Between Non-Competitors, Guidelines on the Definition of Relevant Market and Guidelines on the Voluntary Notification of Agreements, Concerted Practices and Decisions of Associations of Undertakings may be directly relevant to the business dealings and practices in the pharmaceutical industry.

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

The national authority that enforces the Competition Law in Turkey is the Authority, a legal entity with administrative and financial autonomy. The Authority consists of the Competition Board (the Board), Presidency and Service Departments. As the competent body of the Authority, the Board is responsible for, inter alia, reviewing or resolving mergers and investigating or deciding on anti-competitive conduct and agreements. The Board consists of seven members and is seated in Ankara. The service departments consist of five technical enforcement units and five technical support units. There is a 'sectoral' job definition for each technical unit. There is no other specific authority that investigates or decides on pharmaceutical mergers and anti-competitive effects of conduct or agreements in the pharmaceutical sector.

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

In the case of a proven anti-competitive conduct or agreement, the undertakings concerned shall be separately subject to fines of up to 10 per cent of their Turkish turnover generated in the financial year preceding the date of the fining decision (if this is not calculable, the turnover generated in the financial year nearest to the date of the fining decision will be taken into account). Employees or managers of the undertakings or association of undertakings that had a determining effect on the creation of the violation are also fined up to 5 per cent of the fine imposed on the undertaking or association of undertakings. After the recent amendments, the new version of the Competition Law now makes reference to article 17 of the Law on Minor Offences to require the Board to take into consideration factors such as the level of fault and the amount of possible damage in the relevant market, the market power of the undertakings within the relevant market, the duration and recurrence of the infringement, the cooperation or driving role of the undertakings in the infringement, the financial power of the undertakings and compliance with the commitments in determining the magnitude of the monetary fine.

In line with this, the Regulation on Monetary Fines for Restrictive Agreements, Concerted Practices, Decisions and Abuses of Dominance sets out detailed guidelines as to the calculation of monetary fines applicable in the case of an antitrust violation. The Regulation on Monetary Fines applies to both cartel activity and abuse of dominance, but does not cover illegal concentrations. Fines are calculated by first determining the basic level, which is between 2 and 4 per cent for cartels and 0.3 and 3 per cent for other violations; aggravating and mitigating factors are then factored in. The Regulation on Monetary Fines also apply to managers or employees that had a determining effect on the violation (such as participating in cartel meetings and making decisions that would involve the company in cartel activity), and provides for certain reductions in their favour.

In addition to the monetary sanctions, the Board is authorised to take all necessary measures to terminate the restrictive agreement, to remove all de facto and legal consequences of every action that has been taken unlawfully, and to take all other necessary measures in order to restore the level of competition and status as before the infringement. Furthermore, such a restrictive agreement shall be deemed as legally invalid and unenforceable with all its legal consequences. Similarly, the Competition Law authorises the Board to take interim measures until the final resolution on the matter, in case there is a possibility for serious and irreparable damages.

The sanctions that could be imposed under the Competition Law are administrative in nature. Therefore, the Competition Law leads to administrative fines (and civil liability) but not to criminal sanctions. That said, there have been cases where the matter had to be referred to a public prosecutor after the competition law investigation is complete. On that note, bid-rigging activity may be criminally prosecutable under articles 235 et seq of the Turkish Criminal Code. Illegal price manipulation (ie, manipulation through misinformation or other fraudulent means) may also be condemned by up to two years of imprisonment and a civil monetary fine under article 237 of the Turkish Criminal Code.

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?

Private parties can seek to obtain competition-related remedies. Even though an antitrust matter is primarily adjudicated by the Board, enforcement is also supplemented by private lawsuits. In private suits, antitrust violators are adjudicated before regular courts. Due to a treble damages clause allowing litigants to obtain three times their loss as compensation, private antitrust litigations increasingly make their presence felt in the antitrust enforcement arena. Most courts wait for the decision of the Board and build their own decision on that decision (eg, *Ford/Şahsuvaroğlu*, 99-58/624-398, 21 December 1999; *Peugeot/Maestro*, 06-66/885-255, 19 September 2006).

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?

Yes. The Authority may conduct sector-wide inquiries as part of its competition advocacy role. Examples of such inquiries include the recent oil sector report and the ongoing retail sector inquiry concerning the retailing of fast-moving consumer goods.

The Authority has been working on a sector inquiry into the pharmaceutical sector for a long time. The sector inquiry has not finished and the study report has not been published yet. Therefore, the results are still unknown. Initial indications suggest that the focus of the project is mostly on the regulatory framework and practices of governmental authorities. As part of the inquiry, the Authority has sent out questions to certain public bodies (including the Ministry of Health and the Social Security Organisation) as well as the market players.

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

The Authority is the general competent national authority and there are currently no sector-specific competition rules that apply to the pharmaceutical sector.

If the rules or regulations put in place by other regulatory authorities conflict with competition laws or raise competition law concerns, the Authority may use its competition advocacy powers to make non-binding recommendations to the relevant governmental authorities, which may or may not follow such recommendations. The Authority uses the same powers to issue opinions on legislation currently in force or on draft legislation. In the past, the Authority issued several opinions regarding the pharmaceutical sector, mostly to the Ministry of Health.

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

Yes. Similar to article 101(3) of the Treaty of the Functioning of the European Union (TFEU), article 5 of the Competition Law provides that the prohibition contained in article 4 may be declared inapplicable in the case of agreements between undertakings which contribute to improving the production or distribution of products or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefits and which do not impose restrictions which are not indispensable to the attainment of these objectives and do not afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products concerned. This individual exemption test is done on a case-by-case basis and the Board does give weight and effect to industrial-policy type arguments, to the extent they are relevant to the conditions of individual exemption.

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

There is interplay between non-governmental organisations and the Authority. Non-governmental organisations, such as trade associations, can and do bring their antitrust complaints before the Authority. Private antitrust litigation by non-governmental organisations is not a common feature of Turkish antitrust enforcement.

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?

Sector-specific features of the pharmaceutical industry such as product innovation, research and development (R&D), pricing, and distribution or licensing requirements play an important role in the Authority's review of mergers. In practice, the market definition and substantive tests rely heavily on such sector-specific features (eg, *Zentiva/PPF*, 9 July 2008, 08-44/608-233).

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

The Board's Guideline on the Definition of the Relevant Market provides that demand substitution, supply substitution and potential competition should be considered when defining the relevant market. Typically, demand-side substitutability is the main reference point in market definition tests.

In cases that concern the pharmaceutical industry, the Board typically uses Intercontinental Medical Statistics' data and Anatomical Therapeutic Chemical (ATC) product classification. The ATC classification is hierarchical and has 16 categories (A, B, C, D etc), each with up to four levels. The first level (ATC 1) is the most general and the fourth level (ATC 4) is the most detailed. The Board usually relies on the third level of the ATC classification (ATC 3), which allows medicines to be grouped in terms of their therapeutic indications (ie, their intended use), as a starting point for inquiring about product market definition in competition cases (eg, *Actavis/ Roche*, 15 November 2007, 07-86/1082-418; *UCB/Schwarz Pharma* 14 December 2006, 06-90/113-335; *Solvay/BTG*, 6 December 2006, 06-87/1134-332). There have been cases, albeit rarely, where the Board has also taken into account ATC 4 classifications or has opted for a narrower market definition than the ATC 3 classification (*Novartis/ Ebewe Spezial-Pharma*, 17 June 2010, 10-44/783-260).

The Board consistently defines the relevant geographical market as Turkey, without further segmentation on the basis of different regions of the country.

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

Concentrations that do not create or strengthen a dominant position and do not significantly impede effective competition in a relevant product market within the whole or part of Turkey are to be cleared by the Board. Article 3 of the Competition Law defines dominant position as 'any position enjoyed in a certain market by one or more undertakings by virtue of which those undertakings have the power to act independently from their competitors and purchasers in determining economic parameters such as the amount of production, distribution, price and supply'. Market shares of about 40 per cent and higher can be considered, along with other factors such as vertical foreclosure or barriers to entry, as an indicator of a dominant position in a relevant product market. However, a merger or acquisition can only be blocked when the concentration not only creates or strengthens a dominant position but also significantly impedes the competition in the whole territory of Turkey or in a substantial part of it, pursuant to article 7 of the Competition Law. Unilateral effects have been the predominant criteria in the Authority's assessment of mergers and acquisitions in Turkey. That said, there have been a couple of exceptional cases where the Board discussed the coordinated effects under a 'joint dominance test' (*Gaziantep Çimento*, 20 December 2005, 05-86/1190-342).

Therefore, the existence of an overlap and the resulting market shares are not in and of themselves sufficient to raise a competition law concern. The structure of the market, potential competition (such as pipeline products or new R&D investments), market positioning of competitors, barriers to entry, growth projections etc, are all important parameters of the dominance and 'significant lessening of competition' tests.

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

There is no specific provision or case law on this matter. That said, potential competition such as pipeline products or new R&D investment is a parameter to be factored in when reviewing a merger.

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

Article 14 of Communiqué No. 2010/4 enables the parties to provide commitments to remedy substantive competition law issues of a concentration under article 7 of the Competition Law. The Board is explicitly given the right to secure certain conditions and obligations to ensure the proper performance of commitments. Pursuant to the relevant guideline, it is at the parties' own discretion whether to submit a remedy. The Board will neither impose any remedies nor ex parte change the submitted remedy. In the event the Board considers

the submitted remedies insufficient, it may enable the parties to make further changes on the remedies. If the remedy is still insufficient to resolve competition problems, the Board may not grant clearance.

The form and content of the divestment remedies vary significantly in practice. Examples of pro-competitive divestment remedies acceptable to the Board include divestitures, ownership unbundling, legal separation, access to essential facilities and obligations to apply non-discriminatory terms (eg, *Glaxo Wellcome/SmithKline Beecham*, 3 August 2000, 00-29/308-175; *DSM NV/Roche*, 11 September 2003, 03-60/730-342.

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?

The acquisition of one or more patents or licences would amount to a concentration within the meaning of Turkish merger control rules, if and to the extent the patent or licence in question amount to an operable asset. The acquisition would be subject to the reporting and approval requirements, subject to the applicable turnover thresholds being met and the transaction resulting in an affected market or bringing about the creation of a joint venture.

Anti-competitive agreements

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

Article 4 of the Turkish Competition Law is akin to and closely modelled on article 101(1) of the TFEU. It prohibits all agreements between undertakings, decisions by associations of undertakings and concerted practices that have (or may have) as their object or effect the prevention, restriction or distortion of competition within a Turkish product or services market or a part thereof. Unlike the TFEU, article 4 does not refer to 'appreciable effect' or 'substantial part of a market' and thereby excludes any de minimis exception. The enforcement trends and proposed changes to the legislation are, however, increasingly focusing on de minimis defences and exceptions.

Article 4 also prohibits any form of agreement that has the potential to prevent, restrict or distort competition. Again, this is a specific feature of the Turkish cartel regulation system, recognising a broad discretionary power of the Board.

Article 4 brings a non-exhaustive list of restrictive agreements that is, to a large extent, the same as article 101(1) TFEU.

Restrictive agreements that do not benefit from the block exemption under the relevant communiqué or an individual exemption issued by the Board are caught by the prohibition in article 4.

A number of horizontal restrictive agreement types, such as price fixing, market allocation, collective refusals to deal (group boycotts) and bid rigging, have consistently been deemed to be per se illegal.

The Turkish antitrust regime also condemns concerted practices, and the Authority easily shifts the burden of proof in connection with concerted practice allegations through a mechanism called 'the presumption of concerted practice'.

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

The pharmaceutical sector has consistently been under close scrutiny by the Board. So far, both allegations of anti-competitive agreements (article 4) and abuse of dominance (article 6) have been investigated. That said, the number of investigations and amount of fines remain relatively low compared to other sectors such as telecommunications, construction materials, automotive, the banking industry, etc. It is fair to say that the focus of the Authority has been more on the medical consumables and medical devices sectors.

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

The answer to this question depends heavily on whether the technology licensing agreement in question benefits from Communiqué No. 2008/2. Communiqué No. 2008/2 is akin to and closely modelled on the Commission Regulation (EC) No. 772/2004 of 27 April 2004 on the application of article 101(3) of the Treaty to categories of technology transfer agreements. Accordingly, factors such as the market shares of the parties (30 per cent for competitors and 40 per cent for non-competitors), contents of the agreement, competition between the parties, etc, would be essential in assessing whether the agreement is anti-competitive. Hard-core restrictions in technology licensing agreements such as price fixing or maintenance, restriction of output, market or territory-sharing are considered anti-competitive. Communiqué No. 2008/2 exempts a broader range of restrictive provisions, if the agreement is between non-competitors.

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

The answer to this question depends heavily on whether the parties to the co-promotion or co-marketing agreement compete with each other at the manufacturing level. If the answer is negative, the agreement might benefit from the block exemption available under Communiqué No. 2002/2. If the answer is affirmative, any restrictive provisions must fulfil the conditions of individual exemption.

In any event, there have been cases where the Board reviewed and analysed co-promotion and co-marketing agreements. These agreements are considered anti-competitive when and to the extent they:

- serve as a tool to fix prices or other sales terms;
- enable the parties to share customers, markets or territories;
- enable the parties to control the output or demand;
- restrict competition by hindering competitors or forcing competitors out of the market or preventing potential new entries (eg, *Abbot-Eczacıbaşı*, 15 March 2007, 07-23/227-75).

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

A number of horizontal restrictive agreement types with actual or potential competitors, such as price-fixing, market allocation, output restriction, collective refusals to deal (group boycotts) and bid rigging, have consistently been deemed to be per se illegal. On the other hand, agreements such as licensing, R&D, co-marketing and co-manufacturing can be exempted from the article 4 prohibition under an effects-based test, since they may bring about economic or technologic efficiencies. Putting in place appropriate confidentiality conditions and Chinese wall separation mechanisms might assist in preventing coordinated behaviour, reducing the exposure risks of collusion or claims of facilitating collusion between the parties. In any event, this issue warrants a case-by-case analysis.

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

Provisions that may serve as a direct or indirect tool to orchestrate resale price maintenance, exclusivity clauses, customer or territory allocations or restrictions, non-compete obligations, provisions that facilitate information exchanges, most-favoured customer clauses are typical examples of vertical arrangements that are most likely to raise competition law concerns. The analysis should be handled in view of Communiqué No. 2002/2. Under Communiqué No. 2002/2, agreements between two or more undertakings operating at different levels of the production or distribution chain are exempted from the article 4 prohibition, provided that they meet the conditions

Update and trends

The Authority has been working intensely on a sector inquiry into the pharmaceutical sector. It is expected that the results of the inquiry will pave the path for a new and better pharmaceutical antitrust enforcement. Initial indications suggest that the focus of the project is mostly on the regulatory framework and practices of governmental authorities.

A noticeable development was announced in the 2012 Competition Law Letter, which has pointed out that this year's 'theme' in competition policy is the practices and policies of the public institutions (such as the Ministry of Health) that impede effective competition in the markets.

Another talking point was the Authority's 'Competition Law Compliance Programme', which indicates the Authority's increasingly welcoming approach towards internal compliance programmes.

mentioned in the Communiqué. The Communiqué brings about a 40 per cent market share threshold so vertical agreements of undertakings with market shares that exceed 40 per cent cannot benefit from the block exemption. Such undertakings may apply to the Authority for an individual exemption or carry out a self-assessment to see if the vertical agreement in question meets the conditions of individual exemption.

Resale price maintenance

Communiqué No. 2002/2 does not exempt agreements that directly or indirectly restrict the buyer's ability and freedom to determine its own resale prices (eg, *Frito-Lay*, 11 January 2007, 07-01/12-7; *Benckiser*, 3 July 2008, 08-43/591-223).

Exclusivity, restrictions on customers/territories

Provisions that extend beyond what is permissible under an appropriately defined exclusive distribution system, such as restriction of passive sales, cannot benefit from the block exemption and may exclude the vertical agreement from the application of Communiqué No. 2002/2 (eg, *Pfizer/Dilek Ecza*, 2 August 2007, 07-63/774-281).

Non-compete obligations

Non-compete obligations for more than five years and non-compete provisions that are designed to remain in effect post-termination cannot benefit from the block exemption (eg, *Yatsan Sünger*, 23 September 2010, 10-60/1251-469; *Boydak*, 2 November 2011, 11-55/1434-509; *BP*, 23 September 2010, 10-60/1261-473; *Industrial Ice-cream*, 15 May 2008, 08-33/421-147).

Other

Other forms of special clauses such as provisions that facilitate information exchanges and most-favoured customer clauses might also raise competition law concerns. Such clauses warrant close consideration and case-by-case analysis.

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

There is no specific statutory provision or case law on this matter. One can reasonably expect that the Authority's upcoming sector review report will discuss this issue.

Anti-competitive unilateral conduct

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

The main legislation applying specifically to the behaviour of dominant firms is article 6 of the Competition Law. It provides that 'any abuse on the part of one or more undertakings, individually or through joint agreements or practices, of a dominant position in a market for goods or services within the whole or part of the country is unlawful and prohibited'.

Article 6 brings a non-exhaustive list of specific forms of abuse, which is, to some extent, similar to article 102 of the TFEU. Accordingly, such abuse may, in particular, consist of:

- directly or indirectly preventing entries into the market or hindering competitor activity in the market;
- directly or indirectly engaging in discriminatory behaviour by applying dissimilar conditions to equivalent transactions with similar trading parties;
- making the conclusion of contracts subject to acceptance by the other parties of restrictions concerning resale conditions such as the purchase of other goods and services or acceptance by the intermediary purchasers of displaying other goods and services or maintenance of a minimum resale price;
- distorting competition in other markets by taking advantage of financial, technological and commercial superiorities in the dominated market;
- limiting production, markets or technical development to the prejudice of consumers.

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

Article 3 of the Competition Law defines dominance as 'the power of one or more undertakings in a certain market to determine economic parameters such as price, output, supply and distribution, independently from competitors and customers'. Enforcement trends show that the Board is increasingly inclined to somewhat broaden the scope of application of the article 6 prohibition by diluting the

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'independence from competitors and customers' element of the definition to infer dominance even in cases of dependence or interdependence (eg, *Anadolu Cam*, 1 December 2004, 04-76/1086-271; *Warner Bros*, 24.3.2005, 05-18/224-66).

The Board considers high market shares as the most indicative factor of dominance. It also takes account of other factors (such as legal or economic barriers to entry, portfolio power and financial power of the incumbent firm) in assessing and inferring dominance.

The wording of article 6 also prohibits abuses of collective dominance. Precedents on collective dominance are neither abundant nor mature enough to allow for a clear inference of a set of minimum conditions under which collective dominance would be alleged. That said, the Board has considered it necessary to establish 'an economic link' for a finding of abuse of collective dominance (see, for example, *Turkcell/Telsim*, 9 June 2003, 03-40/432 -186).

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

Holding a patent would not in and of itself place the undertaking in a dominant position. The dominant position test should be handled in view of the factors mentioned in question 27 above.

The precedents of the Board do not yet include a finding of dominant position or infringement on the basis of a patent or abuse of intellectual property rights.

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

There is no specific case law on this matter. Theoretically speaking, an application for a patent may result in the applicant's antitrust liability if and to the extent:

- the applicant is in a dominant position in the relevant market;
- the application amounts to an abuse; and
- the application is incapable of justification under objective and legitimate reasons.

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

There is no specific precedent or case law on this matter. Theoretically speaking, the answer to question 29 would apply here as well. Misusing the legal proceedings that result from the enforcement of patent rights to prevent the entry of generics might theoretically result in the dominant patent owner's antitrust liability.

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

There is no specific precedent or case law on this matter. Even if they result in the prevention of new market entries, life-cycle management strategies would not raise competition law concerns, if and to the extent they are used for legitimate business purposes such as taking full benefit of the patent system and are capable of justification under objective criteria.

32 Do authorised generics raise issues under the competition law?

The concept of 'authorised generics' is not defined in Turkish pharmaceutical laws. That is because the licensing regulations in Turkey allow only one licence for a formula. However, there appears to be no legal roadblock against the patent owner gaining a head start on the competition by marketing a generic through establishing a new company and an abridged licence application process.

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

Sector-specific features of the pharma industry may provide good objective justifications for conduct that can otherwise be viewed as anti-competitive. For instance, price control regulations and statutory market monitoring mechanisms justify suppliers' attempts to track the products, which might otherwise raise competition law concerns in some other industries (eg, *3M*, 13 March 2007, 07-22/207-66). Similarly, the obligation on manufacturers and wholesalers to keep adequate supply of medicines at all times may justify sales and export restrictions (*Pfizer/Dilek Ecza*, 2 August 2007, 07-63/774-281).

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

In 2011, antitrust enforcement has witnessed a significant increase in the number of Board decisions on competition law infringements in the market for chemistry and chemical products and drugs. The Board decided on 15 cases in 2011 as compared to nine in 2010. Most of the cases relate to customer or territory sharing, refusal to supply and discrimination claims.

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

Antitrust litigation is an increasingly prominent feature of the Turkish antitrust enforcement. Such litigation is rare but increasing in practice. The majority of such lawsuits in Turkish antitrust enforcement rely on refusal to supply allegations. So far, there has not been a follow-on litigation case concerning the pharmaceutical sector.

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