Pharmaceutical Antitrust

In 29 jurisdictions worldwide

Contributing editor
Mélanie Thill-Tayara

2015

GETTING THE DEAL THROUGH

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CONTENTS

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 from 1928. Law No. 3359 on 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 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 licences are provided by the Ministry of Health. It is possible to file for a licence electronically.

Pricing

The pricing of pharmaceuticals is regulated by the Communiqué on the Pricing of Pharmaceutical Products (Official Gazette of 22 September 2007, No. 26651) and the Decree on Pricing of Pharmaceutical Products (Official Gazette of 30 June 2007, No. 26568). 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 60 per cent of the lowest reference country price. The ex-factory price of generics cannot exceed 60 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. It is akin to and closely modelled after Directive No. 2001/83/EC of 6 November 2001 on the Community Code relating to Pharmaceutical Products for Human Use.

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

There are certain restrictions on the distribution of the pharmaceutical products. The Guideline on the Good Distribution Practice of Pharmaceutical Products (Notice of 22 October 1999, No. 48196) includes complementary principles on the Regulation on Pharmaceutical Wholesalers and Products in the Pharmaceutical Wholesalers (Official Gazette of 20 October 1999, No. 23852). According to these principles, processes and procedures for distribution activities should be in writing. All precautions should be taken to control the distribution chain.

Additionally, the Regulation on Pharmaceutical Wholesalers and Products in the Pharmaceutical Wholesalers prohibits retail sales by pharmaceutical wholesalers (article 10) and distribution of certain pharmaceutical products (article 11).

The Drug Tracking System is a unique system based on a data matrix, which enables the Ministry of Health to follow any box of medicine at any pharmacy in the country. According to the Regulation Regarding the Packaging and Labelling of Medicinal Products for Human Use (Official Gazette of 12 August 2005, No. 25904), all the responsible parties having a role in the production and the distribution level of the pharmaceutical products, namely licence and permit holders, warehouses and pharmacies, should adopt certain distribution practices. These practices are as follows:

- licence or permit holders must inform the Drug Tracking System concerning the products' data matrix that they:
  - produce or store to sell;
  - sell;
  - accept for return; and
  - decide to destroy on any grounds;
- warehouses must inform the Drug Tracking System concerning the products that they:
  - buy from the suppliers;
  - trade with the other warehouses whether buying or selling;
  - accept for return and decide to destruct on any grounds;
  - lose in the transportation process; and
  - sell to the pharmacies, and
- pharmacies must inform the Drug Tracking System concerning the products that they:
  - buy;
  - return to the seller;
  - decide to destroy;
  - trade; and
  - sell on any grounds.

3 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 Pharmaceuticals and Medical Devices Authority, a sub-entity 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.

4 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, barring any judicial precedents that take account of the sector-specific aspects of the industry.

Competition legislation and regulation

5 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 (the Competition Law).

The national competition authority for enforcing the Competition Law in Turkey is the Turkish Competition Authority (the 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 general communiqués currently in force (excluding communiqués related to amendments to communiqués and communiqués related to administrative fines): Communiqué No. 2010/4 on Mergers and Acquisitions that Require the Approval of the Competition Board, Communiqué No. 2010/2 on Hearings held in relation to 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. 1998/4 on the procedures and principles to be pursued in pre-notifications and authorisation applications to be filed with the Authority in order for acquisitions via privatisation to become legally valid, Communiqué No. 1997/5 on the Conclusion of the Organisation of the Authority, Communiqué No. 2012/2 on the Application Procedure for Competition Law Infringements, Block Exemption Communiqué No. 2013/3 on Specialisation Agreements and Communiqué No. 2013/2 on the procedures and principles to be pursued in pre-notifications and authorisation applications to be filed with the Authority in order for acquisitions via privatisation to become legally valid.

The following is a list of all the guidelines currently in effect: the guidelines on remedies that are acceptable by the Authority in merger and acquisition transactions; the guidelines on undertakings concerned, turnover and ancillary restraints in mergers and acquisitions; the guidelines on the definition of relevant market; the guidelines on certain toll manufacturing agreements between non-competitors; the guidelines on the voluntary notification of agreements, concerted practices and decisions of associations of undertakings; the guidelines on the explanation of the Block Exemption Communiqué on vertical agreements; the guidelines on certain subcontracting agreements between non-competitors; the guidelines on the explanation of the Block Exemption Communiqué on vertical agreements and concerted practices in the motor vehicle sector; the guidelines explaining of the application of articles 4 and 5 of the Law on Protection of Competition on Technology Transfer Agreements; the guidelines explaining the Regulation on Active Cooperation for Discovery of Cartels; the guidelines on horizontal cooperation agreements; the guidelines on the assessment of horizontal merger and acquisitions; the guidelines on the assessment of non-horizontal mergers and acquisitions; the guidelines on mergers and acquisitions transactions and the concept of control; the guidelines on the general principles of the exemption; and the guidelines on the assessment of exclusionary conduct by dominant undertakings.

Additionally, the Authority has released a draft of the Regulation on Administrative Monetary Fines for public comment, but this draft has not been enacted yet.

The Draft Proposal for the Amendment of the Competition Law (Draft Law) was submitted to the Grand National Assembly of Turkish Republic on 23 January 2014, but this draft has also not been enacted yet.

6 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), Block Exemption Communiqué No: 2013/3 on Specialisation Agreements, the guidelines on the assessment of exclusionary conduct by dominant firms, the guidelines on the general principles of the exemption, the guidelines on horizontal cooperation agreements, the guidelines on certain toll manufacturing agreements between non-competitors, the guidelines on the definition of relevant market and the 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.

7 Which authorities investigate and decide on pharmaceutical mergers and the anti-competitive nature 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), and the 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 eight technical support units. There is a 'sectoral' job definition for each technical unit and all competition law-related issues of the pharmaceutical sector are reviewed by the Third Supervision and Enforcement Department. 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.

8 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 (or both) 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. The Competition Law 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, etc, 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 0.5 and 3 per cent for other violations; aggravating and mitigating factors are then factored in. The Regulation on Monetary Fines also applies 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 article 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.

9 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. Turkey is one of the exceptional jurisdictions where a treble damages clause exists in the law. 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/Sahsuvaroglu*, 99-58/624-398, 21 December 1999; *Peugeot/Maestro*, 06-66/885-255, 19 September 2006). The majority of private lawsuits in Turkish antitrust enforcement rely on refusal to supply allegations.

10 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. The Authority has completed the full sector inquiry for the pharmaceutical sector after three years and published the Pharmaceutical Sector Report (the Report) on 27 March 2013.

The report is akin to the Pharmaceutical Sector Inquiry Report of the EC. It mainly focuses on sector specific regulations such as licensing, pricing, refunding conditions of pharmaceuticals and the status and the effects of patents in the market. It underlines that the applicable regulations are closely modelled with EC regulations; however, unlike the practice in Europe there are still remarkable delays in the completion of licencing applications that cause barriers for market entries. Therefore, it suggests amending the relevant legislation and shortening the application terms for an efficient competition environment despite positive progress in the release of the products on the market. The Report also indicates that the patent protection is a major necessity for the sector. It further underlines that the Board will be more active for commercialisation agreements and will evaluate the risk of coordination more cautiously.

11 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.

12 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 that 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 that do not impose restrictions that 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, as confirmed by the recently enacted guidelines.

13 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 (eg, the Association of Research-Based Pharmaceutical Companies, the Pharmaceutical Manufacturers Association of Turkey) 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 very common feature of Turkish antitrust enforcement as yet, though the number of relevant cases is increasing.

Review of mergers

14 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, *Pfizer*, 7 April 2011, 11-22/386-120; *Zentiva/PPF*, 9 July 2008, 08-44/608-233).

15 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, *Valeant*, 11 July 2013, 13-44/552-246; *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; *Actavis/Alpharma*, 15 December 2005, 05-84/1151-331). 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; *GlaxoSmithKline*, 3 June 2004, 04-40/453-114; *Pfizer/Sanovel*, 18 March 2004, 04-20/206-42).

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

16 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 all 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' (*Henkel*, 20 January 2009, 09-03/47-16; *Petrol Sanayi Derneği*, 20 September 2007, 07-76/907-345; *Gaziantep Çimento*, 20 December 2005, 05-86/1190-342; *TEB*, 18 September 2000, 00-35/393-220).

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.

17 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.

18 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 to 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 remedies acceptable to the Board include divestitures, ownership unbundling, legal separation, licensing requirements, access to essential facilities and obligations to apply non-discriminatory terms (eg, *Novartis*, 8 July 2010, 10-49/929-327; *Novartis*, 26 May 2005, 05-36/450-103; *Syngenta*, 29 July 2004, 04-49/673-171; *Glaxo Wellcome/SmithKline Beecham*, 3 August 2000, 00-29/308-175; *DSM NV/Roche*, 11 September 2003, 03-60/730-342.

19 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 amounts to an operable asset. The acquisition would be subject to the reporting and approval requirements, subject to the applicable turnover thresholds being met.

Anti-competitive agreements

20 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'.

21 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 the Board has conducted nine investigations against wholesalers and suppliers over allegations of anti-competitive agreements (article 4) and abuse of dominance (article 6). 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 Board has been more on the medical consumables and medical devices sectors.

22 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.

23 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 (eg, *Biovesta/Abdi İbrahim*, 27 November 2012, 12-60/1597-581);
- enable the parties to share customers, markets or territories;
- enable the parties to control the output or demand; or

- restrict competition by hindering competitors or forcing competitors out of the market or preventing potential new entries (eg, *Merck Sharp*, 18 July 2012, 12-38/1086-345; *Abbot/Eczacıbası*, 15 March 2007, 07-23/227-75; *Sandoz/Eli Lilly*, 2 August 2007, 07-63/776-282; *Eczacıbaşı/Gül*, 12 September 2014, 14-32/647-284; *Abdi İbrahim*, 9 May 2013, 13-27/368-170).

The guidelines on horizontal cooperation agreements lay down the basics of the competition law analysis of similar co-promotion and co-marketing agreements, including the above-listed principles.

24 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 technological efficiencies. Putting in place appropriate confidentiality conditions and Chinese wall separation mechanisms may 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.

25 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 and 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 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; *Bakara İlaç*, 31 March 2010, 10-27/394-147, *Anadolu Elektrik*, 23 June 2011, 11-39/838-262, *Reckitt Benckiser*, 13 June 2013, 13-36/468-204). However, indications in practice suggest that the Board is increasingly unlikely to adopt a dismissive approach towards resale price maintenance behaviour (*Dogati*, 22 October 2014, 14-42/764-340).

Exclusivity, restrictions on customers and 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, *Mey İçki*, 12 June 2014, 14-21/410-178; *Unilever*, 15.05.2008, 08-33/421-147; *Novartis*, 04 July 2012, 12-36/1045-332; *Turkcell*, 6 June 2011, 11-34/742-230; *Pfizer/Dilek Ecza*, 2 August 2007, 07-63/774-281; *Karbogaz*, 23 August 2002, 02-49/634-257).

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, *Sanofi Aventis*, 2 November 2012, 12-59/1570-571; *Boehringer*, 27 October 2011 11-54/1389-497; *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 Icecream*, 15 May 2008, 08-33/421-147; *Takeda*, 3 April 2014, 14-13/242-107).

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 analyses.

26 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.

Anti-competitive unilateral conduct

27 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 superiority in the dominated market; and
- limiting production, markets or technical development to the prejudice of consumers.

28 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 '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 March 2005, 05-18/224-66).

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

The wording of article 6 also prohibits abuse 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; *Biryay*, 17 July 2000, 00-26/292-162).

29 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 28.

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.

Update and trends

After a long wait on the sidelines, the Draft Law was submitted to the Grand National Assembly of the Turkish Republic on 23 January 2014. The Draft Law introduces a de minimis rule, which enables the Board to ignore certain cases that do not exceed a certain market share or turnover threshold, and introduces the EU's SIEC (significant impediment of effective competition) test to the Turkish control regime in place of the current dominance test. It also contains settlement provisions for certain cases, which are intended to be used by case handlers allowing them to advise the Board in instances where the parties subject to the investigation did not commit violations. In those cases, the Board can decide to wholly or partially end an investigation. 2014 was not a year of extraordinary developments in pharmaceutical sector. Although there have been certain preliminary investigations, the Board did not conclude any full-fledged investigations in 2014. The year in review did not witness many competition law infringement allegations in the pharmaceutical sector compared to previous years.

Recent cases

Recently, the Board has cleared the proposed acquisition of the consumer health business of Novartis AG by GlaxoSmithKline plc (GSK) The decision is conditional upon the divestiture of assets in consumer health businesses. Under the proposed acquisition, GSK committed to divest several assets, namely GSK's NiQuitin business and Novartis' Vectavir business within six months and with all of its components, and to inform the Board about the process. The clearance is conditional upon the parties ensuring full compliance with these commitments. The Board has not yet published the reasoned decision.

In *Novartis/GSK*, (14-43/796-357; 29 December 2014), the Board has cleared the proposed acquisition of the oncology business portfolio (excluding manufacture of the products) of GSK by Novartis.

In *Novo Nordisk*, (14-35/685-302; 19 November 2014), the defendant allegedly abused its dominant position by refusal to enter into contract with the complainant and by discriminating against pharmaceutical warehouses. The Board decided by a majority of votes to close the case without initiating a full-fledged investigation.

In *SGK/TEB*, (14-07/132-59; 19 February 2014), SGK and TEB allegedly abused their dominant position by exclusively distributing prescriptions and allocating them among pharmacies through the protocol of 1 February 2012. The Board decided to finalise the case without initiating a full-fledged investigation. Two of the complaints filed repeal suits at the Administrative Court. The Administrative Court rejected one of the cases on the grounds that the protocol was in compliance with the current legislation, the issue could only be examined by a repeal suit and the Board did not have the authority to decide on this issue.

30 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 that:

- 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.

31 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 30 would apply here as well. Misusing the legal proceedings that result from the enforcement of patent rights to prevent the entry of generics (sham litigation) might theoretically result in the dominant patent owner's antitrust liability.

32 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.

33 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.

34 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).

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35 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.

The year in review witnessed a decrease in the number of Board decisions on competition law infringements in the market for chemistry and chemical products and drugs. In 2014, the Board decided 26 pharma cases including eight preliminary investigations, 13 exemption applications, five merger filings and one remanded decision after appeal, compared with 39 cases in 2013. Most of the cases relate to customer or territory sharing, refusal to supply and discrimination claims. Figures for 2015 were not available at the time of writing.

36 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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