Pharmaceutical Antitrust 2019

Contributing editors
Mike Cowie, George Gordon and Mélanie Thill-Tayara

LEXOLOGY®
Getting The Deal Through

Publisher
Tom Barnes
tom.barnes@lbresearch.com

Subscriptions
Claire Bagnall
claire.bagnall@lbresearch.com

Senior business development managers
Adam Sargent
adam.sargent@gettingthedealthrough.com

Dan White
dan.white@gettingthedealthrough.com

Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 3780 4147
Fax: +44 20 7229 6910

First published 2008
Twelfth edition
ISBN 978-1-83862-095-0

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

Pharmaceutical Antitrust

2019

Contributing editors
Mike Cowie, George Gordon and Mélanie Thill-Tayara
Dechert LLP

Lexology Getting The Deal Through is delighted to publish the twelfth edition of Pharmaceutical Antitrust, which is available in print and online at www.lexology.com/gtdt.

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

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on Romania.

Lexology Getting The Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.lexology.com/gtdt.

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

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Mike Cowie, George Gordon and Mélanie Thill-Tayara of Dechert LLP, for their assistance with this volume. We also extend special thanks to Daniel L Wellington and Neely B Agin of Norton Rose Fulbright, who contributed the original format from which the current questionnaire has been derived, and who helped to shape the publication to date.

LEXOLOGY
Getting The Deal Through

London
June 2019

Reproduced with permission from Law Business Research Ltd
This article was first published in August 2019
For further information please contact editorial@gettingthedealthrough.com

Contents

Turkey

Gönenç Gürkaynak and K Korhan Yıldırım
ELİG Gürkaynak Attorneys-at-Law

PHARMACEUTICAL REGULATORY LAW

Regulatory framework

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

The primary 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 and 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 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 Licence Application Pending Products (Official Gazette of 23 May 2005, No. 25823). This regulation, in turn, is closely modelled on 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 and 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 3 July 2015, No. 29405). 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.

Regulatory authorities

2 | Which authorities are entrusted with enforcing these 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 (the Authority).

Pricing

3 | Are drug prices subject to regulatory control?

Pursuant to the Communiqué on the Pricing of Pharmaceutical Products (Official Gazette of 29 September 2017, No. 30195), drug prices are subject to regulatory control. The Communiqué comprises a reference system that takes France, Greece, Italy, Portugal and Spain as primary reference countries for drug prices. To set ex-factory drug prices in Turkey, the Communiqué first determines a real reference price in euros, following a procedure that categorises drugs under four combinations, which are variations of a drug being export or Turkey product and original or generic. The procedure aims to set the real reference price as the lowest ex-factory price valid in the reference countries. After a real reference price is set for a drug, a reference price in euros is determined under three classifications:

- export or Turkey product original drugs;
- Turkey product generic drugs; and
- export generic drugs.

In light of this classification, article 6 of the Communiqué calculates the reference price in euros as 60, 80 or 100 per cent of the set real reference price, according to various specifications.

With respect to calculated reference price, article 7 of the Communiqué calculates that an ex-factory drug price in Turkish lira is

calculated in accordance with the officially announced exchange rate for each year by the Price Evaluation Commission. While the Price Evaluation Commission announces the annual rate, according to the Amendment to the Decree on Pricing of Pharmaceutical Products (Official Gazette of 14 February 2019, No. 30686), as with the Turkish euro equivalent of €1 for the pricing of pharmaceutical products, the adjustment coefficient rate shall be 60 per cent of the annual average of the euro exchange rate as announced by the Central Bank of the Republic of Turkey.

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.

Regulatory control began in 1985 in Turkey, when the first version of the Communiqué on the Pricing of Pharmaceutical Products was published in the Official Gazette (16 January 1985, No. 18637).

Distribution

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

There are certain restrictions on the distribution of 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 25 April 2017, No. 30048), all the responsible parties with 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 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.

Intersection with competition law

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

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

Legislation and enforcement authorities

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

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

The national competition authority for enforcing the Competition Law in Turkey is 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):

- Block Exemption Communiqué No. 2017/3 on Vertical Agreements and Concerted Practices in the Motor Vehicle Sector;
- Communiqué No. 2019/1 on Increase of the Lower Threshold for Administrative Fines Specified in Paragraph 1 of Article 16 of the Law No. 4054 on the Protection of Competition (valid until 31 December 2019);
- Block Exemption Communiqué No. 2016/5 on Research and Development Agreements (Communiqué No. 2016/5);
- Block Exemption Communiqué No. 2013/3 on Specialisation Agreements;
- 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;
- Communiqué No. 2012/2 on the Application Procedure for Competition Law Infringements;
- Communiqué No. 2010/4 on Mergers and Acquisitions that Require the Approval of the Competition Board (the Board);
- Communiqué No. 2010/2 on Hearings held in relation to the 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; and
- Communiqué No. 1997/5 on the Formation of the Organisation of the Authority.

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 No. 2017/3;
- 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;
- the guidelines on the assessment of exclusionary conduct by dominant undertakings;
- the guidelines on evaluation of competition; and
- the guidelines on vertical agreements.

There is a potential draft law proposal on the matter. The Draft Proposal for the Amendment of the Competition Law (the Draft Law) was submitted to the Grand National Assembly of Turkish Republic on 23 January 2014. In 2015, the Draft Law became obsolete owing to the general elections in June 2015. As reported in the 2015 Annual Report of the Authority, the Authority has requested the re-initiation of the legislative procedure concerning the Draft Law.

Public enforcement and remedies

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

In the case of a proven anticompetitive conduct or agreement, 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 to restore the level of competition and status as before the infringement. Similarly, the Competition Law authorises the Board to take interim measures until the final resolution on the matter in case there is a possibility of serious and irreparable damage.

Furthermore, undertakings and associations of undertakings condemned by the Board for violating article 4 through an anticompetitive conduct or agreement may be given administrative fines of up to 10 per cent of their Turkish turnover generated in the financial year preceding the date of the fining decision (or, if this is not calculable, in the financial year nearest the date of the fining decision). Employees or members of the executive bodies of the undertakings or association of undertakings that had a determining effect on the creation of the violation would also be fined up to 5 per cent of the fine imposed on the undertaking or association of undertaking.

The Regulation on Monetary Fines for Restrictive Agreements, Concerted Practices, Decisions and Abuses of Dominance (the Regulation on Fines) is applicable for calculation of monetary fines in the case of antitrust violations. According to the Regulation on Fines, fines are calculated by first determining the base fine, which in the case of non-cartel behaviour ranges between 0.5 per cent and 3 per cent, and 2 per cent and 4 per cent for cartel behaviour of the company's turnover in the financial year preceding the date of the decision to impose a fine. If this is not calculable, the turnover for the financial year nearest to the date of the decision is to be considered in calculation. 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.

Private enforcement and remedies

8 Can remedies be sought through private enforcement by a party that claims to have suffered harm from anticompetitive conduct or agreements implemented by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

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. Private antitrust litigations increasingly make their presence felt in the antitrust enforcement arena owing to a treble damages clause allowing litigants to obtain three times their loss as compensation. 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; and *Peugeot/Maestro*, 06-66/885-255, 19 September 2006). The majority of private lawsuits in Turkish antitrust enforcement rely on refusal to supply and cartel allegations. However, this is a growing area as private antitrust lawsuits become more common.

Sector inquiries

9 Can the antitrust authority conduct sector-wide inquiries? If so, have such inquiries ever been conducted into the pharmaceutical sector and, if so, what was the main outcome?

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 and published the Pharmaceutical Sector Report (the Report) on 27 March 2013.

The report is akin to the Pharmaceutical Sector Inquiry Report of the European Commission (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 licensing 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.

Health authority involvement

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

There is interplay between other regulatory bodies such as the Pharmaceuticals and Medical Devices Authority and the Authority. While the Pharmaceuticals and Medical Devices Authority does not have specific tasks directly related to the application of competition law, the fact that it has the power and duty of a sector regulator with the ability to set prices at the initial level of trade (where the profit margins in different levels of distribution is already regulated) essentially means it has role in the functioning of the market. Still, the Authority has the power to apply competition law in regulated markets just like in any other markets. However, if necessary, it may also enter into collaboration agreements with other market regulators to define their relationship in keeping the competitive health in the market.

NGO involvement

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

There is an 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

Thresholds and triggers

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

There is no sector-specific threshold regime determined for the pharmaceutical sector, therefore concentration transactions in the pharmaceutical sector are subject to general thresholds. To that end, pursuant to article 7 of Communiqué No. 2010/4 on Mergers and Acquisitions Requiring the Approval of the Competition Board, a transaction would be notifiable if one of the below turnover thresholds is triggered:

- the aggregate Turkish turnover of the transaction parties exceeding 100 million Turkish lira and the Turkish turnover of at least two of the transaction parties each exceeding 30 million Turkish lira;
- the Turkish turnover of the transferred assets or businesses in acquisitions exceeding 30 million Turkish lira and the worldwide turnover of at least one of the other parties to the transaction exceeds 500 million Turkish lira; or
- the Turkish turnover of any of the parties in the merger exceeds 30 million Turkish lira and the worldwide turnover of at least one of the other parties to the transaction exceeds 500 million Turkish lira.

13 Is the acquisition of one or more patents or licences subject to merger notification? 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 reporting and approval requirements, provided that applicable turnover thresholds are being met.

Market definition

14 How are the product 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 (ATC1) is the most general and the fourth level (ATC4) is the most detailed. The Board usually relies on the third level of the ATC classification (ATC3), 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, *Baxalta/Shire*, 30 March 2016, 16-12/189-84; *Allergan/Teva*, 20 November 2015, 15-41/679-241; *Reckitt Benckiser*, 7 July 2015, 15-28/344-114; *Valeant*, 11 July 2013, 13-44/552-246; *Otsuka Pharma/Abdi*, 28 August 2012, 12-42/1256-408; and *Actavis/Roche*, 15 November 2007, 07-86/1082-418). There have been cases, albeit rarely, where the Board has also taken into account ATC4 classifications or has opted for a narrower market definition than the ATC3 classification (*Roche*, 16 November 2016, 16-39/642-288; *Roche/MTS*, 13 October 2016, 16-33/569-247; *Daiichi Sankyo/Aksel*, 8 September 2016, 16-30/504-225; *Novartis/Ebewe Spezial-Pharma,* 17 June 2010, 10-44/783-260; and *GlaxoSmithKline*, 3 June 2004, 04-40/453-114).

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

Sector-specific considerations

15 Are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

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, *Allergan Plc*, 20 November 2015, 15-41/679-241; *Pfizer*, 7 April 2011, 11-22/386-120; and *Zentiva/PPF*, 9 July 2008, 08-44/608-233).

Addressing competition concerns

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

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.

Horizontal mergers

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

> *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/horizontal 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; and *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.

Product overlap

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

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.

Potential competition is formed by firms operating in the relevant market with a potential to increase their capacity in the short term, and with a potential to enter into the relevant market, even though it is not currently active. The analysis of potential competition in the Board's past decisions usually focuses on the discussion of barriers to entry (see, eg, *Johnson and Johnson*, 28 July 2015, 15-32/461-143; *Henkel*, 20 January 2009, 09-03/47-16; *Condat SA Henkel*, 4 July 2007, 07-56/659-229). While evaluating the competitive effects of a merger filing, the Board considers whether an entry to the relevant market is possible and a potential entry to the relevant market would avoid the anticompetitive effect of the merger transaction, as also indicated in Guidelines for Horizontal Mergers.

Remedies

19 | 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. If 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; *DSM NV/Roche*, 11 September 2003, 03-60/730-342; and *Glaxo Wellcome/SmithKline Beecham*, 3 August 2000, 00-29/308-175). As a general rule, structural remedies take precedence over behavioural remedies. To that end, behavioural remedies can be considered in isolation only if structural remedies are impossible to implement and behavioural remedies are beyond doubt as effective as structural remedies. For behavioural remedies to be accepted alone, such remedies must produce results as efficient as divestiture, such as the following:

> *it must be sufficiently clear that lowering of entry barriers by the access rights given through the proposed remedy will lead to the entry of new competitors in the market and significant lessening of competition will be eliminated (paragraph 77 of the Guidelines on Acceptable Remedies).*

ANTICOMPETITIVE AGREEMENTS

Assessment framework

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

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) of the 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'.

Technology licensing agreements

21 To what extent are technology licensing agreements considered anticompetitive?

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 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 anticompetitive. Hardcore restrictions in technology licensing agreements such as price-fixing or maintenance, restriction of output, market or territory sharing are considered anticompetitive. Communiqué No. 2008/2 exempts a broader range of restrictive provisions, if the agreement is between non-competitors.

Co-promotion and co-marketing agreements

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

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

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.

Other agreements

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

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. However, 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.

Issues with vertical agreements

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 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, *Reckitt Benckiser*, 13 June 2013, 13-36/468-204; *Anadolu Elektrik*, 23 June 2011, 11-39/838-262; *Bakara İlaç*, 31 March 2010, 10-27/394-147; *Benckiser*, 3 July 2008, 08-43/591-223; and *Frito-Lay*, 11 January 2007, 07-01/12-7). 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 and 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, *Trakya Cam*, 2 December 2015, 15-42/704-258; *Mey İçki,* 12 June 2014, 14-21/410-178; *Novartis*, 4 July 2012, 12-36/1045-332; *Turkcell*, 6 June 2011, 11-34/742-230; *Unilever*, 15 May 2008, 08-33/421-147; *Pfizer/Dilek Ecza*, 2 August 2007, 07-63/774-281; and *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 Ice-cream*, 15 May 2008, 08-33/421-147; and *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.

Patent dispute settlements

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

There is no specific statutory provision or case law on this matter.

Joint communications and lobbying

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

Article 4 of Law No. 4054 prohibits agreements and concerted practices between companies, and decisions and practices of trade associations that have as their object or effect or likely effect the prevention, distortion or restriction of competition directly or indirectly in a particular market for goods or services. Therefore, joint communications or lobbying actions may raise competition law concerns if they entail exchange of commercially sensitive information by competitors (*12 Banks*, 8 March 2013, 13-13/198-100; *Automotive Sector*, 18 April 2011, 11-24/464-139; *Association of Manufacturers of Fertilizer*, 8 February 2002, 02-07/57-26; *Coal Cartel* 11 September 2003, 03-60/733-343; and *Ceramic Cartel* 24 February 2004, 04-16/123-26).

There have been cases where the Board reviewed and analysed joint communications or lobbying actions. These are considered anticompetitive when and to the extent they:

- serve as a tool to fix prices or other sales terms (eg, *Turkish Pharmacists' Association*, 10 July 2007, 07-58/674-233);
- enable the parties to share customers, markets or territories;
- enable the parties to control the output or demand; or
- restrict competition by hindering competitors, forcing competitors out of the market or preventing potential new entries (eg, *TEB (Turkish Pharmacists' Association)*, 9 July 2010, 10-49/912-321; and *TEB (Turkish Pharmacists' Association)*, 18 September 2000, 00-35/393-220).

The guidelines on horizontal cooperation lay down the basics of the competition law analysis of joint communications or lobbying actions between competitors, including the above-listed principles.

Public communications

27 To what extent may public communications constitute an infringement?

The answer to question 20 would apply here as well. A pharmaceutical company or trade association would be subject to antitrust liability to the extent that they violate articles 4 or 6 of Law No. 4054 during public communications by, for instance, price signalling.

Exchange of information

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

The pharmaceutical market is indeed considerably more transparent than other markets. Transparent markets are generally considered to be more suitable for anticompetitive exchanges. However, this does not readily apply to the pharmaceutical sector since the industry is highly regulated. Types of strategic information that are highly sought after in other markets simply do not carry the same weight in the pharmaceutical sector because of the regulatory interests. As detailed above, pricing is closely monitored by the authorities and regulated by the law-maker.

Disclosure of relationships regarding clinical trials, etc, would not lessen the competition in the market to the extent that these disclosures do not contain information that would be directly relevant to the competition.

ANTICOMPETITIVE UNILATERAL CONDUCT

Abuse of dominance

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

The 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.

De minimis thresholds

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

No. There is no de minimis threshold for unilateral conducts in Turkish competition law (eg, *İstanbul Grand Bus Terminal Operation*, 23 September 2005, 05-60/893-242). Having said that, the Authority is increasingly inclined to accept de minimis defences in the enforcement of articles 4 and 6.

Market definition

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

Yes, the framework explained under Question 14 applies in assessing both dominance cases and concentrations.

Establishing dominance

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

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; and *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, eg, *Turkcell/Telsim*, 9 June 2003, 03-40/432-186; and *Biryay*, 17 July 2000, 00-26/292-162).

IP rights

33 To what extent can an application for the grant or enforcement of a patent or any other IP right (SPC, etc) expose the patent owner to liability for an antitrust violation?

There is no specific case law on this matter. Theoretically, 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.

There is no specific precedent or case law on this matter. Theoretically, the answer to question 31 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.

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

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. If a life-cycle management strategy exceeds the objective need of restricting competition to obtain its efficiencies, it may be interpreted as raising certain competition law concerns.

Communications

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

Communications and recommendations aimed at the public or healthcare professionals mostly consist of promotional activities. These activities pertaining to the promotion of medicinal products must be performed in accordance with the rules laid down in the Regulation on Promotional Activities of Medicinal Products (Official Gazette of 3 July 2015, No. 29405). They are surveilled by the Turkish Medicine and Medical Device Institution. Promotional activities aimed at the public are prohibited under the Regulation on Promotional Activities of Medicinal Products, which ipso facto leads pharmaceutical companies to direct their promotional activities at healthcare professionals. According to the Sectoral Report of the Authority, promotional activities for informational purposes promote competition in the market whereas promotional activities for brand awareness purposes have the tendency to restrict competition as they may cause market foreclosure. Namely, pharmaceutical companies settled in the market may use promotional activities for brand awareness as a strategy to increase the cost of market entry and hamper activities of other undertakings in the market. Promotional activities for brand awareness purposes may also have the tendency to trigger antitrust liability to the extent that they violate article 6 of Law No. 4054. Although there is no specific precedent or case law on this matter, Sectoral Report of the Authority suggests that healthcare professionals prescribe active substances instead of pharmaceutical brands. However, legislative endeavours do not yet include any efforts on that front.

Authorised generics

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

The concept of 'authorised generics' is not defined in Turkish pharmaceutical laws. This 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.

Restrictions on off-label use

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

Off-label medicine consumption is illegal in Turkey. According to the Guidelines on Off-Label Medicine Use published by the Pharmaceuticals and Medical Devices Authority pursuant to Notice 2009/36 of the Ministry, off-label medicine consumption is subject to Pharmaceuticals and Medical Devices Authority's permission. The Guidelines on Off-Label Medicine Use provides exemption from requirement of permission for certain medicines that it determines in Exhibits 4 and 5. Thus, theoretically, a patent holder can exercise its patent right for limiting off-label use, only if its product is in the scope of the exemption or after permission is granted for such product.

There is no specific case law or legislation on this matter in Turkish competition law enforcement. To the extent that the patent holder lawfully exercises the right to comply with the Guidelines on Off-Label Medicine Use, the Board would be unlikely to intervene and find an antitrust violation. Existence of health and safety concerns for off-label consumption of certain drugs may be deemed as a valid justification for exercising patent right to limit off-label use of certain drugs. Having said that, one cannot altogether rule out the possibility that the Board might not consider exercising patent right as an objective and legitimate reason to limit off-label use of a drug, since it may deprive consumers from accessing affordable treatment and their and doctors' freedom to choose and apply a treatment. For that reason, such conduct might be classified as an abuse of dominant position, if the patent holder undertaking holds the dominant position in the market.

Pricing

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

The wording of article 6 does not consist of any definition or exemplification on pricing conducts to raise antitrust risks. By taking the Guidelines on the Assessment of Exclusionary Conduct by Dominant Undertakings (the Guidelines) as a reference, one can assert that a pricing conduct will raise antitrust risks, when the undertaking:

- is in dominant position;
- exploits its market power against consumer welfare; and
- does not have an objective necessity or an efficiency to implement such conduct and, even if it had, restricted competition only to the extent needed for that reason.

The Guidelines state some examples of pricing conduct that have exclusionary effects (eg, predatory pricing, price/margin squeeze, rebate systems, price discrimination, excessive pricing). There are also exploitative and discriminatory pricing conducts that raise antitrust risks.

Accordingly, the Board may interpret excessive prices as abusive. Excessive pricing is a company setting prices significantly above the competitive level by exploiting market power, thereby transferring welfare of consumers to itself. Turkish case law, in this context, defines excessive pricing as an abuse of dominant position and the Board has various precedents considering excessive pricing as an antitrust infringement.

The Board applies a twofold economic value test to determine the existence of excessive pricing. At the first stage, the test requires comparison of cost and set price, thus it measures profit margin; then, the set price is compared with itself in different conditions or the price of competing product or services. However, the Board mostly utilises comparison of set prices with price of competing product or services (second stage of the test), especially when it is not possible to measure the profit margin (eg, *Viessmann*, 15 May 2017, 17-16/223-93; and *Congresium,* 27 October 2016, 16-35/604-269).

Even though its profit margin was negative, the Board imposed a fine against Belko, since its price differences with its equivalent services were 50–60 per cent (*Belko*, 6 April 2001, 01-17/150-39). The Board does not have a constant threshold of reasonableness for profit margin or price difference to impose a fine owing to excessive pricing. It did not find excessive pricing, when Biletix' profit margin was between 11 and 18 per cent (*Biletix*, 1 March 2007, 07-18/164-54) or MTS' price difference was between 25 and 30 per cent with a substitute product (*MTS*, 26 May 2006, 06-36/462-124). However, it found that Tüpraş set excessive prices when its prices were 15 per cent different from the price of competitors in Italy and 30 per cent different from its own export prices (*Tüpraş*, 17 January 2014, 14-03/60-24). Hence, one can argue that the Board takes the three bullet points articulated above into consideration along with the economic value test while determining the infringement.

Sector-specific issues

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

Sector-specific features of the pharma industry may provide good objective justifications for conduct that can otherwise be viewed as anticompetitive. 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). Similarly, designating distributors to attend public tenders on an exclusive capacity has also been found to serve the public good by keeping hospital inventories stocked (eg, *Roche*, 16 November 2016, 16-39/642-288; *Roche*, 13 October 2016, 16-33/569-247; and *Daiichi*, 8 September 2016, 16-30/504-225).

ELİG GÜRKAYNAK Attorneys at Law

Gönenç Gürkaynak
gonenc.gurkaynak@elig.com

K Korhan Yıldırım
korhan.yildirim@elig.com

Çitlenbik Sokak No:12
Yıldız Mahallesi
Beşiktaş 34349
Istanbul
Turkey
Tel: +90 212 327 17 24
www.elig.com

UPDATE AND TRENDS

Emerging trends and hot topics

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

The past year did not see any groundbreaking cartel cases or record fines for cartel activity in the pharmaceutical sector. The majority of cases comprised individual exemption applications of pharmaceutical distributors that are opting for exclusivity schemes for certain distribution channels such as public tenders. The year in review did not witness many competition law infringement allegations in the pharmaceutical sector compared with previous years.

The Authority recently released the Block Exemption Communiqué on Research and Development Agreement No. 2016/5 (the Communiqué), which was published in the Official Gazette, dated 16 March 2016, and numbered 29655. The Communiqué is relevant and important for the pharmaceutical sector, considering the importance of research and development activities for the sector. The Communiqué enhanced legal certainty and thus provided undertakings with a clearer foresight on exemption conditions through explicit and extensive definitions, compared with the definitions in Communiqué No. 2003/2. For instance, the definitions for terms such as 'potential competitor' and 'competing undertaking', which were excluded from Communiqué No. 2003/2, have been included in the Communiqué. Additionally, the term 'specialisation in exploitation' is defined more comprehensively, by pursuing harmony with the EU Regulation on R&D Agreements. In line with the EU Regulation on R&D Agreements, the terms 'know-how' and 'trade secrets', which were not included within the scope of Communiqué No. 2003/2, have been defined in the Communiqué.

Most recent cases

In the *Roche Müstahzarları* decision (26 September 2018; 18-34/577-283), the Board rendered its final decision regarding the full-fledged investigation conducted against Roche Müstahzarları San AŞ. to determine whether the relevant undertaking has violated Law No. 4054 by way of stipulating pharmaceutical warehouses to sign the agreement that includes export prohibition clause, refusal of supply conducts towards the complainant who did not accept the relevant condition and putting pressure on other pharmaceutical warehouses for not selling Roche products to the complainant. The full-fledged investigation was initiated based on the annulment of the Board's decision (17 June 2010; 10-44/785-262), upon the 13th Council of State's decision (16 December 2016; 2010/4617 E, 2016/4241 K). As a result of the full-fledged investigation, the Board decided that Roche Müstahzarları San AŞ did not violate Law No. 4054 and therefore there is no need to impose any administrative monetary fines on the relevant undertaking.

In the *Sanofi/Abdi İbrahim* decision (31 May 2018; 18-17/299-149), the Board reviewed the negative clearance/exemption request regarding the contract manufacturing agreement between Sanofi and Abdi İbrahim. In this decision, the Board relied on ATC3 level for insulin products in the evaluation of the relevant product market affected by the relevant agreement. Upon conducting its substantial assessment on the relevant agreement, the Board decided to grant an individual exemption.

Other titles available in this series

Acquisition Finance
Advertising & Marketing
Agribusiness
Air Transport
Anti-Corruption Regulation
Anti-Money Laundering
Appeals
Arbitration
Art Law
Asset Recovery
Automotive
Aviation Finance & Leasing
Aviation Liability
Banking Regulation
Cartel Regulation
Class Actions
Cloud Computing
Commercial Contracts
Competition Compliance
Complex Commercial Litigation
Construction
Copyright
Corporate Governance
Corporate Immigration
Corporate Reorganisations
Cybersecurity
Data Protection & Privacy
Debt Capital Markets
Defence & Security Procurement
Dispute Resolution
Distribution & Agency
Domains & Domain Names
Dominance
e-Commerce
Electricity Regulation
Energy Disputes
Enforcement of Foreign Judgments
Environment & Climate Regulation
Equity Derivatives
Executive Compensation & Employee Benefits
Financial Services Compliance
Financial Services Litigation
Fintech
Foreign Investment Review
Franchise
Fund Management
Gaming
Gas Regulation
Government Investigations
Government Relations
Healthcare Enforcement & Litigation
High-Yield Debt
Initial Public Offerings
Insurance & Reinsurance
Insurance Litigation
Intellectual Property & Antitrust
Investment Treaty Arbitration
Islamic Finance & Markets
Joint Ventures
Labour & Employment
Legal Privilege & Professional Secrecy
Licensing
Life Sciences
Litigation Funding
Loans & Secured Financing
M&A Litigation
Mediation
Merger Control
Mining
Oil Regulation
Patents
Pensions & Retirement Plans
Pharmaceutical Antitrust
Ports & Terminals
Private Antitrust Litigation
Private Banking & Wealth Management
Private Client
Private Equity
Private M&A
Product Liability
Product Recall
Project Finance
Public M&A
Public Procurement
Public-Private Partnerships
Rail Transport
Real Estate
Real Estate M&A
Renewable Energy
Restructuring & Insolvency
Right of Publicity
Risk & Compliance Management
Securities Finance
Securities Litigation
Shareholder Activism & Engagement
Ship Finance
Shipbuilding
Shipping
Sovereign Immunity
Sports Law
State Aid
Structured Finance & Securitisation
Tax Controversy
Tax on Inbound Investment
Technology M&A
Telecoms & Media
Trade & Customs
Trademarks
Transfer Pricing
Vertical Agreements

Also available digitally

lexology.com/gtdt

ISBN 978-1-83862-095-0