Pharmaceutical Antitrust

Contributing editors
Marta Giner Asins and Yann Anselin

2017

GETTING THE DEAL THROUGH

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Pharmaceutical Antitrust 2017

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Norton Rose Fulbright LLP

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CONTENTS

Introduction 5
Marta Giner Asins and Yann Anselin
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Brazil 7
Alexandre Ditzel Faraco, Ana Paula Martinez and Mariana Tavares de Araujo
Levy & Salomão Advogados

China 13
Susan Ning and Zhifeng Chai
King & Wood Mallesons

European Union 20
Andrea Hamilton, Wilko van Weert and David Henry
McDermott Will & Emery Belgium LLP

Finland 27
Salla Mäntykangas-Saarinen and Hanna Paloheimo
Castrén & Snellman Attorneys Ltd

France 32
Christophe Hénin and Julie Vasseur
Intuity

Germany 40
Maxim Kleine and Tim Schaper
Norton Rose Fulbright (Germany) LLP

India 47
Samir R Gandhi, Kamya Rajagopal and Kadambari Chinoy
AZB & Partners

Israel 51
David E Tadmor, Shai Bakal and Itai Cohen
Tadmor & Co Yuval Levy & Co Attorneys-at-Law

Italy 57
Enzo Marasà and Elisa Stefanini
Portolano Cavallo

Japan 63
Yusuke Nakano
Anderson Mōri & Tomotsune

Korea 68
Hwa Soo Chung, Kyungsun Kyle Choi and Luke Shin
Kim & Chang

Mexico 73
Ricardo Arturo Pons Mestre, Ernesto Federico Algaba Reyes and Martin Michaus-Fernandez
Hogan Lovells BSTL

Poland 77
Sławomir Karasiński and Natalia Wolska
Fortak & Karasiński Legal Advisors LLP

Portugal 83
Joana Gomes dos Santos
Caiado Guerreiro, Sociedade de Advogados, SP, RL

Spain 88
Helmut Brokelmann and Mariarosaria Ganino
Martínez Lage, Allendesalazar & Brokelmann

Turkey 94
Gönenç Gürkaynak and K Korhan Yıldırım
ELİG, Attorneys-at-Law

Ukraine 101
Alexey Pustovit
Asters

United Kingdom 106
Peter Scott, Ian Giles, Susanna Rogers and Maria Campbell
Norton Rose Fulbright LLP

United States 115
Daniel L Wellington and Neely B Agin
Norton Rose Fulbright US LLP

Preface

Pharmaceutical Antitrust 2017

Tenth edition

Getting the Deal Through is delighted to publish the tenth edition of *Pharmaceutical Antitrust*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

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 **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured.

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.gettingthedealthrough.com.

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.

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, Marta Giner Asins and Yann Anselin of Norton Rose Fulbright LLP, for their continued assistance with this volume.

GETTING THE DEAL THROUGH

London
April 2017

Introduction

Marta Giner Asins and Yann Anselin
Norton Rose Fulbright LLP

This new edition of *Getting the Deal Through – Pharmaceutical Antitrust* will provide readers with an updated, thorough overview of the application of antitrust law to the pharmaceutical sector worldwide. The pharmaceutical sector remains an important area for antitrust enforcement in nearly all major jurisdictions, where concerns polarise around traditional subjects, such as patent settlements, public procurement and life-cycle management strategies, but increasingly also on emerging issues, such as the growing importance of innovation competition, drug prices and, in particular, excessive pricing and e-health platforms and databases.

In terms of mergers, competition authorities are likely to continue focusing on innovation and potential competition, particularly in the US and EU. In February 2016, the Federal Trade Commission (FTC) required generic drug manufacturers Lupin Ltd and Gavis Pharmaceuticals LLC (Gavis) to divest the rights and assets associated with two generic drugs to allow Lupin's acquisition of Gavis to proceed, although neither party had yet reached the market. Key to the FTC's assessment was that the two companies were among the few players likely to enter the market in the near future. In the European Union, the EU Commission assessed 'pipeline to pipeline' competition in the recent *Mylan/Meda* merger of 2016. In *GSK/Novartis* the Commission went one step further by extending its analysis of pipeline pharmaceutical products beyond those that are in advanced stages of development (phase III products), to fully assess the impact of the merger on competing clinical research programmes for ovarian and skin cancer and, ultimately, on innovation competition. The Commission also emphasised the importance of innovation competition with respect to biosimilars in the *Pfizer/Hospira* merger of 4 August 2015, in which it considered that because there is room for differentiation strategies and non-price competition between biosimilars, the number of differentiated biosimilars for price competition is important as it is less likely that few biosimilar competitors can deliver significant price reductions than typically observed for generics. E-health platforms and databases are also raising an increasing number of antitrust concerns evolving around data access and interoperability, aspects which were analysed by the Commission in the *Sanofi/Google* JV in February 2016.

Outside the merger arena, the pressure to lower drug prices will drive enforcement and private actions against unilateral and concerted conduct across jurisdictions.

Two years after the Daraprim scandal, excessive prices remain a clear enforcement priority of the new administration in the US where litigation is expected to be particularly intense. The year 2017 started with Mallinckrodt's agreement to pay US$100 million to settle charges by the FTC and five states for having taken advantage of its monopoly in the market for ACTH drugs by raising the price per vial from US$40 per vial in 2001 to more than US$34,000 per vial. According to the complaint, Mallinckrodt felt threatened that a competitor would obtain the US rights to Synacthen, a competing drug used in Europe and Canada to treat infantile seizures and allegedly outbid several competitors to obtain the US rights to Synacthen from Novartis AG. Also in January of 2017, three makers of diabetes treatments were named in a class action lawsuit in a federal court in Massachusetts for having increased the price of insulin by over 150 per cent during the past five years. Generics are not shielded from risk as shown by the first charges resulting brought by the DOJ against two former senior generic pharmaceutical executives for their roles in conspiracies to fix prices, rig bids and allocate customers for certain generic drugs following a two-year investigation into the generic drug market.

The situation is no different in the EU. In the UK, Pfizer and Flynn Pharma were fined nearly £90 million in December 2016 for 'excessive and unfair' pricing to the NHS after increasing the cost of an anti-epilepsy drug by up to 2,600 per cent overnight, a decision following the decision taken on 25 October 2016 by the Competition and Markets Authority to launch another investigation relating to suspected excessive prices in the supply of certain pharmaceutical products. In September 2016, the Italian Competition Authority issued a €5 million fine to the pharmaceutical company Aspen, accusing it of threatening the agency with stopping the supply of vital oncology medicines for patients in the Italian market if they refused to increase the drugs' price, a decision that prompted the Spanish Competition Authority to initiate proceedings against Aspen on similar grounds in February 2017. In Ukraine, an investigation was recently closed and resulted in fines for both pharmaceutical companies and distributors, accused among others of implementing non-transparent retroactive rebate schemes allowing distributors to overcharge pharmaceutical in tender proceedings. Outside the EU, in China, the National Reform and Development Council is also conducting a nationwide drug-pricing investigation on pharmaceutical companies and has clearly signaled the will to target and sanction excessive pricing. This subject is clearly a global trend and is to be watched in the following years, although its modalities will be different in each local jurisdiction, since practices are very strongly conditioned by the local pricing system and regulations.

In this context, patent settlements remain a risky endeavour considering the strict case law developments on both sides of the Atlantic. The US First Circuit confirmed on 22 February 2016 in *In re Loestrin 24 FE Antitrust Litigation* that non-cash reverse payments (in this case an agreement by the originator not to market an authorised generic product during the generic challenger's 180-day exclusivity period to settle litigation under the Hatch-Waxman Act and in exchange for delayed generic entry) are subject to antitrust scrutiny under the Sherman Act. Meanwhile, in the EU the General Court confirmed in *Lundbeck* that patent settlements can constitute a restriction 'by object' although the upcoming *Servier* judgments may provide further guidance for undertakings in the coming months. These concepts have also been adopted by other authorities around the world, such as the Japan Fair Trade Commission, which in 2015 published a report alerting pharmaceutical companies in Japan to the reverse payment issue.

More generally, companies should pay close attention to any type of life-cycle management strategy, including misleading representations and slandering. By way of example, in Israel, the Central District Court recently sanctioned Sanofi, in a case echoing the EU *AstraZeneca* precedent, for misleading the patent office by knowingly submitting incorrect information regarding the circumstances of the discovery that led to its patent application. Similarly, in Brazil, the Council for Economic Defence Tribunal found, in June 2015, that Eli Lilly abused its rights by presenting misleading information to courts. A further investigation is also pending in relation to alleged conduct by AstraZeneca to deter generic entry, including ring-fencing practices regarding its IP rights and 'sham litigations' before courts. In France, in October 2016, the French Supreme Court upheld Sanofi's generic denigration fine imposed by the French Competition Authority in 2013.

Public tenders are another obvious area of enforcement risks as shown in Spain, Portugal or Mexico, as is medicine distribution. In China, the NDRC fined US device manufacturer Medtronic US$17 million for engaging in resale price maintenance in December 2016 and, in the same month, the Shanghai Price Bureau fined Smith & Nephew for similar conduct. In Germany, the Federal Cartel Office raided drug wholesalers (some of whom had already been sanctioned for similar conduct in 2006) suspected of illegal collusion and in Spain, the above-mentioned investigation against Aspen initiated by the Spanish Competition Authority also involves a suspected vertical agreement with a distributor. Cross-distribution of medicine is also trending in the EU. Following referral by the Italian Council of State (the ICS) in the *Lucentis/Avastin* case, the Court of Justice will provide guidance on the assessment of alleged market-sharing agreements and clarify key issues at the intersection of antitrust and pharmaceutical regulation, including to what extent parties to a licensing agreement can be regarded as competitors when the licensee company operates on the market solely by virtue of that agreement, and whether national competition authorities can define the relevant market autonomously with regard to the content of marketing authorisations (Case C-179/16, *Hoffmann-La Roche*). Still in the EU, parallel trade remains an ever-contentious area, as shown by the number of recent or pending internal market cases before the Court of Justice (See, eg, cases C-277/15, *Servoprax* (language obstacles to parallel imported medical products), C-297/15, *Ferring Lægemidler* (repackaging and use trademark law) and C-148/15, *Deutsche Parkinson Vereinigung* (fixed prices in Germany for prescription-only medicine)).

It is also interesting to note that other authorities are following the trend of the EU Commission and using sector inquiries to analyse the pharmaceutical sector. For example, in India, in 2015, the CCI invited entities to carry out a study on the pharmaceutical and healthcare industry, the result of which has not been published yet.

Brazil

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The main pieces of legislation that set out the regulatory framework for the pharmaceutical sector in Brazil are:

- Law No. 5,991/1973, which provides for the sanitary control of drugs, medicines, pharmaceutical and related inputs marketing;
- Law No. 6,360/1976, which provides for the sanitary control to which medicines, drugs, pharmaceutical and related inputs are subject;
- Law No. 9,782/1999, which defines the national system of sanitary control and creates the National Health Surveillance Agency (ANVISA);
- Law No. 9,787/1999, which amends Law No. 6,360/1976 by providing for generic drugs;
- Decree No. 3,675/2000, which provides for special measures related to the registration of generic drugs;
- Law No. 10,742/2003, which defines rules for the pharmaceutical sector and creates the Chamber of Drug Market Regulation (CMED);
- Decree No. 4,766/2003, which regulates CMED's attributions and operation;
- Decree No. 4,937/2003, which regulates article 4 of Law No. 10,742/2003 to establish the criteria for the adjustment of drugs' prices; and
- Decree No. 8,077/2013, which regulates the conditions for the functioning of companies subject to sanitary licensing, and the registration, control and monitoring of products subject to sanitary control, according to Law No. 6,360/1976.

Moreover, there are several regulatory acts from ANVISA regarding matters such as drug registration, licences for pharmaceutical laboratories and other agents of the pharmaceutical production chain, and price regulation, the latter made by CMED.

CMED regulates prices for original, branded generic and generic drugs, and regularly publishes price lists. Prices of new drugs are defined based on overall reference values and a basket of other countries' market prices.

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

ANVISA is responsible for regulating activities related to the distribution of pharmaceutical products in Brazil. Some of the rules issued by the agency on distribution activities are:

- ANVISA's Resolution No. 320/2002, which determines duties of companies that distribute pharmaceutical products;
- ANVISA's Resolution No. 204/2006, which establishes that all undertakings that perform distribution activities, among other things, must comply with the guidelines provided in the Technical Rules of Good Practices for Distribution and Fractioning of Pharmaceutical Inputs; and
- ANVISA's Resolution No. 39/2013, which provides for the administrative proceedings for granting of the Certificate on Good Distribution Practices.

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

The most relevant aspects of the Brazilian regulatory framework to the application of competition law to the pharmaceutical sector aim to promote competition between originator and generic drugs. These are:

- doctors within the public health system shall consider the active ingredient rather than the brand in the prescription;
- the government shall organise bids listing the active ingredient rather than the brand;
- the entry price of generics has to be at least 35 per cent under the price of the originator product (prices are regulated by CMED); and
- originator companies shall supply samples to generic competitors to allow them to produce generics.

The intersection between the pharmaceutical sector and competition law is widely recognised by the Brazilian authorities. In 2013, ANVISA and the Council for Economic Defence (CADE) executed a technical cooperation agreement, with the goal of enhancing the relationship between the two agencies, through, for example, workshops, technical visits, and joint studies and research. The agreement also provides for the exchange of information, reports, databases and other relevant documents.

Competition legislation and regulation

4 Which legislation sets out competition law?

Competition law and practice in Brazil is primarily governed by Law No. 12,529 of 30 November 2011 (Law No. 12,529/2011 or the Competition Law), which entered into force on 29 May 2012. The competition law has consolidated the investigative, prosecutorial and adjudicative competition functions into one independent agency, CADE.

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

CADE's structure includes a tribunal composed of six commissioners and a president; a Directorate-General for Competition (DG); a General-Attorney's Office; and an economics department. With respect to merger enforcement, the DG is responsible for clearing simple transactions and challenging complex cases before the tribunal, while CADE's tribunal is responsible for adjudicating complex cases challenged by the DG, by the tribunal itself or by third parties. The DG is also the chief investigative body in matters related to anticompetitive practices. CADE's tribunal is responsible for adjudicating the cases investigated by the DG. All of CADE's decisions are subject to judicial review.

Certain anticompetitive conduct (primary cartel conduct) is also a crime in Brazil. Federal and state public prosecutors are responsible for enforcing the Criminal Statute. Also, the police (local or federal) may initiate investigations of anticompetitive conduct and report the results of their investigation to CADE and prosecutors, who may indict

the individuals. The administrative and criminal authorities have independent roles and powers, and may cooperate on a case-by-case basis.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

Brazil's competition law applies to corporations, associations of corporations and individuals. For corporations, fines range between 0.1 and 20 per cent of the company's or group of companies' pre-tax turnover in the economic sector affected by the conduct in the year prior to the beginning of the investigation.

Apart from fines, CADE may also:

- order the publication of the decision in a major newspaper at the wrongdoer's expense;
- prohibit the wrongdoer from participating in public procurement procedures and obtaining funds from public financial institutions for up to five years;
- include the wrongdoer's name in the Brazilian Consumer Protection List;
- recommend that the tax authorities block the wrongdoer from obtaining tax benefits;
- recommend that the IP authorities grant compulsory licences of patents held by the wrongdoer;
- order a corporate spin-off, transfer of control or sale of assets; and
- prohibit an individual from exercising market activities on its behalf or representing companies for five years.

The law also includes a broad provision allowing CADE to impose any 'sanctions necessary to terminate harmful anticompetitive effects'. CADE's wide-ranging enforcement of this provision may prompt judicial appeals.

Regarding anticompetitive conduct in the pharmaceutical sector, CADE's tribunal has traditionally imposed fines of up to 5 per cent of the relevant turnover.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

At the administrative level, private parties can petition CADE to be admitted to the administrative proceedings aimed at investigating the anticompetitive conduct or agreement as an 'interested third party'. Such parties have the ability to file arguments or documents with CADE, but the antitrust authority is responsible for imposing the remedies deemed necessary.

Moreover, private parties that were victims of anticompetitive conduct or agreement may seek recovery of actual damages and lost earnings, and moral damages by filing a judicial lawsuit. Courts may also order other types of relief, such as court injunctions to cease the illegal conduct. The scope of such orders is broad. Possible examples include ordering a defendant to stop selling a product, to change pricing conditions or any other contractual provisions.

There are already damages claims filed by generic drugs against originator companies pending before judicial courts and this could represent an additional area of concern when dealing with non-ordinary life-cycle management strategies in Brazil.

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

Brazil's antitrust authorities may conduct sector-wide inquiries. According to the Competition Law, CADE's tribunal and DG can retain professionals to conduct analysis, studies and inspections as well as request information from any individual, authority, agency and public or private entities deemed necessary. CADE's economic department can also, by its own initiative or at the request of CADE's tribunal or DG, conduct studies and economic opinions. The Competition Law also provides that the Economic Monitoring Office is the agency responsible for competition advocacy, and may, among other measures, develop studies examining competition in specific sectors of the national economy.

Similarly to other jurisdictions, there is an increasing number of cases in the pharmaceutical sector being reviewed by CADE, and a sector inquiry was conducted in 2009 and 2010 by the then Secretariat of Economic Law (SDE), following the initiatives of the European Commission and the US Federal Trade Commission. The SDE sent out questionnaires to approximately 40 originator companies questioning practices related to patent extensions. Brazilian Law 5,772/1971 explicitly prohibited drug patenting. On the other hand, the Agreement on Trade-Related Aspects of Intellectual Property Rights created an obligation for Brazil to protect drug patents, with transitional rules ('pipeline' patents). The 'pipeline' allowed patent requests to be automatically approved based on the date of the first foreign filing; the maximum period for patent protection is 20 years under Brazilian law.

A number of branded pharmaceutical companies resorted to judicial courts to extend their protection, defending theories such as only the first valid foreign filing should be considered for the purposes of determining the duration of the patent protection (at the time of the sector inquiry, there were over 37 cases pending before the Superior Court of Justice). The issue was settled in April 2010, when the Superior Court of Justice decided that the date of the first foreign filing is the valid one, even if the filing was later withdrawn (*Viagra* case).

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

Any individual or entity, including non-government groups, can file a complaint before CADE's DG in relation to alleged anticompetitive practices. Non-government groups can also be requested to provide information in proceedings related to merger review or anticompetitive conducts. Moreover, non-government groups can also petition CADE to be admitted to different proceedings as an 'interested third party', as mentioned in question 7.

Federal, state and municipal governments, public prosecutors, any governmental consumer protection agency, publicly held entities and private non-profit organisations that have in their bylaws the protection of consumer or antitrust rights and were incorporated at least one year before the filing can stand in class actions related to anticompetitive conducts.

Historically, Pró Genericós, the Brazilian association of generic companies, has been playing a very active role before CADE, bringing most of the complaints challenging life-cycle management strategies on the part of originator companies.

Review of mergers

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

While analysing mergers concerning the pharmaceutical industry, CADE usually considers sector-specific features only in the more complex cases.

Some of these features are listed in the Procedural Guideline for setting and performing the antitrust analysis of the relevant drug markets, issued by the former SDE. According to this document, the relevant market definition for cases involving the pharmaceutical industry should take into account the following features:

- medicines are subject to different and specific legislation regarding their production, distribution and advertising;
- prescription-bound and over-the-counter (OTC) medicines may follow different competition patterns;
- the strong information asymmetry leads to high advertising costs, especially for OTC products, which may sometimes cause product differentiation and market segmentation;
- there are relevant barriers to entry including patent protection; and
- the strength of generic drugs and strategic brand-positioning for some medicines should also be taken into account.

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

The product market is generally defined by CADE as including all the products and services considered substitutable by consumers because of their features, prices and usage. A relevant market of the product could encompass a certain number of products and services that present physical, technical or business characteristics that recommend the grouping.

CADE has consistently taken as a starting point for market definition purposes the anatomical therapeutic chemical (ATC) classification system devised by the European Pharmaceutical Marketing Research Association (EphMRA) and maintained by EphMRA and IMS Health.

In most of the cases, CADE has adopted the fourth ATC level (ATC4) as the criterion to define the relevant product market. However, CADE has also stated that it may be necessary to analyse pharmaceutical products at a higher, lower or mixed level of ATC classification and based on the effective substitutability of the products in order to define the relevant market. In most of those exercises, CADE took into account ATC3 and the drug's therapeutic use.

Also, CADE has considered in the past that originator drugs and their generic copies belong to the same relevant product market, as generics can effectively substitute originator drugs after patent expiry, especially if the regulatory system encourages switching – as is the case in Brazil.

Furthermore, in its decisional practice, CADE has defined separate products markets for out-licensing, supply of active pharmaceutical ingredients and contract manufacturing.

From a geographic perspective, CADE has traditionally defined the market to be national in scope, given the limited weight of imports, the high level of regulation, the obligation for laboratories and medicines to be registered before ANVISA and the fact that pharmaceutical companies generally offer their medicines throughout the country with uniform price policies.

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

CADE traditionally follows a five-step review process provided for in the Horizontal Merger Guidelines, consisting of:

(i) definition of relevant market;
(ii) determination of the parties' market share;
(iii) assessment of the probability of the parties exercising market power following the transaction;
(iv) examining the efficiencies; and
(v) evaluating the net effect on welfare.

Based on this review process, the authorities will consider whether perceptible efficiencies resulting from the merger are likely to reduce or reverse adverse effects arising from the transaction. It is incumbent upon the merging firms to substantiate efficiency claims so that CADE can verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved, how each would enhance the merged firm's ability and incentive to compete, and why each would be merger-specific.

CADE's case law shows that efficiencies arguments have limited weight in the agency's decision-making process. Historically, whenever CADE has reached item (iv), the transaction was either blocked or cleared subject to substantial remedies.

Non-competition issues, such as industrial policy or public interest, are not traditionally factored into the review process.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

The Competition Law presumes market power to exist if the parties jointly hold a share of at least 20 per cent of the market. CADE's recently published Guidelines on Horizontal Mergers describe threshold levels of market concentration that raise concerns about the possible exercise of market power in a few ways: by a single firm unilaterally, when that firm has a market share of at least 20 per cent; or through coordination of firms (collective dominance) in a market in which the four-firm concentration ratio is at least 75 per cent and the resulting firm has a market share of at least 10 per cent. If the market concentration exceeds either of those levels, CADE proceeds to step three (market power exercise). Following the US or the EC standards, CADE's guidelines also consider the Herfindahl-Hirschman Index (HHI) as a measure of concentration.

For example, when reviewing Merger Case No. 08700.009834/2014-09 (*Anovis and União Química*), CADE considered that no competition concerns would arise if the combined market share was under 20 per cent. For the two ACT4 category classes for which the resulting concentration was over 20 per cent, CADE resorted to the HHI index, which indicated the high market share was in fact prior to the transaction and was little affected by it. As concentrations were over 50 per cent, CADE took a conservative approach and proceeded with the analysis of the possibility of exercise of market power, which would not be significantly affected by the merger, and thus cleared the case. More recently, in Merger Case No. 08700.005093/2016-59 (*Sanofi and Boehringer Ingelheim*), despite finding concentration above 20 per cent in the market segments involved in the transaction and a HHI variation above 200 points, CADE cleared the case without restrictions due to: (i) the fact that the parties' products included in the same market segment were not close substitutes; and (ii) that there is a great number of companies with high market share in the segments affected. A similar approach was taken by CADE while reviewing Merger Case No. 08700.006159/2016-28 (*Pfizer and AstraZeneca*). Even though the transaction resulted in a high market share in some of the affected markets – and in some cases the HHI variation was also relevant – CADE cleared the transaction without restrictions because, among other things: (i) Pfizer's high market share was only identified considering the scenario in terms of value, which could be related to drugs over which the company previously had patent; (ii) the market share of the parties in terms of units was very low; (iii) new drugs entered the market and there is projection of new products; and (iv) the presence of important competitors in the affected markets.

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

An overlap concerning products that are being developed may be problematic in some scenarios, such as: if the patent rights related to the active principles of the developing product may increase current and potential costs of third parties, and strengthening the merging parties' dominant position, increasing barriers to entry; or if there is a risk that the merged entity will terminate or reduce the development of the product to avoid competition with products currently being marketed by the other party to the transaction. In more recent years, CADE has reviewed a number of joint ventures between pharmaceutical companies aimed at developing new products in Brazil. In such cases, competition concerns arose when the partnership resulted in potential elimination of future competition between the parties, preventing them from entering the market alone.

When Pfizer and Orygen filed the formation of a joint venture aimed at producing and selling up to five biosimilar products in Brazil (Merger Case No. 08700.005601/2014-37), CADE assessed the estimated market shares and potential horizontal overlaps with regard to each relevant ATC4 class. Since there were no relevant horizontal overlaps, CADE identified no risk of potential competition elimination, leading to the approval of the transaction with no conditions.

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

The Competition Law allows CADE to take whatever measures deemed necessary to ensure the merger would not impact competition, and there is a preference for adopting structural rather than behavioural remedies. If CADE finds a transaction to be harmful to competition, it may block it or accept remedies, particularly divestitures of production facilities, stores, distribution networks or brands. Under the Competition Law, parties can negotiate undertakings with CADE to remedy perceived competition issues. Parties can offer undertakings from the day of filing up to 30 days following the challenge of the transaction before the tribunal by the DG.

For example, in *Sanofi/Medley* (Merger Case 08012.003189/2009-10), CADE cleared the transaction in 2010 on the condition that the merged entity would sell three drugs to market players with less than 15 per cent market share to improve competition. The merger entity would otherwise have over 50 per cent of the problematic relevant markets, considered to have high entry barriers. The transaction was also viewed as creating portfolio effects. The case also involved the adoption of an interim measure in 2009 aimed to ensure that the parties would preserve the reversibility of the transaction in case CADE ultimately decided to block it or impose remedies (at that time, CADE

did not have a pre-merger review and parties were allowed to close the transaction pending CADE's decision).

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

Law No. 12,529/2011 requires that a transaction be filed in Brazil if the following criteria are met: each of at least two parties to the transaction meet the turnover threshold; the transaction amounts to 'a concentration act'; and the transaction produces effects in Brazil, as defined by article 2 of the Competition Law (effects test).

Brazil's competition law provides for a minimum-size threshold, expressed in total revenues derived in Brazil by each of at least two parties to the transaction. One party must have Brazilian revenues in the last fiscal year of at least 750 million reais and the other party 75 million reais – both the acquirers and sellers, including their whole economic group, should be taken into account.

The Competition Law provides that any 'concentration act' must be submitted to CADE for review, provided that the turnover threshold is met. Whereas the law specifically refers to 'concentration acts', it defines those very broadly as when:

- two or more companies merge;
- one company acquires, directly or indirectly, sole or joint control of another, or even a minority shareholding;
- an absorption of other companies takes place; or
- a joint venture, an associative contract or a consortium is formed.

Finally, the effects test is met whenever a given transaction is wholly or partially performed within Brazil or, if performed abroad, it is capable of producing effects within Brazil. This will be the case if the target to the transaction has a direct or indirect presence within the country or the market is global in scope. Direct presence is achieved through, among other things, a local subsidiary, distributor or sales representative. Although indirect presence is most commonly established through export sales into the country, the possibility that CADE considers third-party sales (eg, via a licensing agreement) as evidence of indirect presence in Brazil cannot be ruled out. Intention to enter the Brazilian market in the near future may also be considered by CADE when assessing the potential effects in the country.

The acquisition of licences of patents would be subject to mandatory filing assuming the criteria set out above are met.

Anticompetitive agreements

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

The basic framework for the assessment of anticompetitive agreements or conducts in Brazil is set by article 36 of Law No. 12,529/2011. Article 36 deals with all types of anticompetitive conduct other than mergers. The Competition Law prohibits acts 'that have as [their] object or effect':

- the limitation, restraint or, in any way, harm to open competition or free enterprise;
- control over a relevant market for a certain good or service;
- an increase in profits on a discretionary basis; or
- engagement in market abuse.

Article 36(3) contains a lengthy but not exhaustive list of acts that may be considered antitrust violations provided they have the object or effect of distorting competition. Potentially anticompetitive practices include resale price maintenance, price discrimination, tying sales, exclusive dealing and refusal to deal.

CADE Resolution 20/1999 specifically provides that exclusivity agreements, refusal to deal, price discrimination and other vertical restraints are not per se infringements in Brazil and shall be assessed under the rule-of-reason test. Annex II of CADE Resolution No. 20/99 (Annex II) outlines 'basic criteria for the analysis of restrictive trade practices', including:

- definition of relevant market;
- determination of the defendants' market share;
- assessment of the market structure, including barriers to entry and other factors that may affect rivalry; and
- assessment of possible efficiencies generated by the practice and balance them against potential or actual anticompetitive effects.

In practice, no case has yet been decided on the basis that harmful conduct was justified by pro-competitive efficiencies.

18 To what extent are technology licensing agreements considered anticompetitive?

Article 36 of Brazil's Competition Law includes as examples of anticompetitive practices conduct performed through the abuse of intellectual property rights, and CADE has been consistently stating that the grant of intellectual property rights may lead to anticompetitive effects (when, for example, a party licenses intellectual property rights to one party and refuses to do the same to its rivals). Restraints involving intellectual property rights are assessed under the rule of reason, therefore, it is likely that the assessment would take into account the specific characteristics of each case, and balance potentially competitive against anticompetitive effects.

In 2013, for example, CADE cleared with conditions four transactions involving licensing agreements between Monsanto and four other companies (Don Mario Sementes, Nidera Sementes, Syngenta and Coodetec – Cooperativa Central de Pesquisa Agrícola) in relation to the development, production and marketing of soybean seed with Mosanto's Intacta RR2 PRO technology. The conditions refer to changes in clauses of the agreement that granted Monsanto the possibility to influence strategic decisions of the licensee companies (eg, the agreement established a compensation mechanism for licensee companies that was based on the sales of the Intacta product and on the sales of certified seeds of Monsanto's competitors).

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

The Antitrust Law provides no clear-cut guidance on the subject. However, since these agreements are reviewed under the rule of reason, it is likely that the assessment would take into account the specific characteristics of each case, and balance potentially pro-competitive and anticompetitive effects.

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

Under article 36 of Law 12,529/2011, agreements with competitors would be an issue if they 'have as [their] object or effect':

- the limitation, restraint or, in any way, harm to open competition or free enterprise;
- control over a relevant market for a certain good or service;
- an increase in profits on a discretionary basis; or
- engagement in market abuse.

Therefore, there is no specific form of agreement that is forbidden a priori by the legislation. Besides their object and effect, CADE will take into consideration the market power held by the involved parties in order to assess the likeliness of antitrust risks. For those agreements that may concern the exchange of commercially sensitive information among competitors, confidentiality provisions will be useful tools to help reduce this exchange and thus avoid further antitrust liability.

Cartel cases, however, are an exception to the assessment under the rule of reason, as CADE historically defined it as a per se conduct. CADE also includes in the cartel definition the exchange of commercially sensitive information that may lead to the change of market conditions, even if an agreement is not reached by the parties.

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

Vertical agreements raise antitrust concerns when they 'have as [their] object or effect':

- the limitation, restraint or, in any way, harm to open competition or free enterprise;
- control over a relevant market for a certain good or service;
- an increase in profits on a discretionary basis; or
- engagement in market abuse.

Article 36(3) contains a lengthy but not exhaustive list of acts that may be considered antitrust violations provided they have the object or effect of distorting competition. Potentially anticompetitive practices include resale price maintenance, price discrimination, tying sales, exclusive dealing and refusal to deal.

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

CADE has recently considered pay-for-delay conduct to be a potential violation of the Competition Law and liability may apply in case a pharmaceutical company settles a patent dispute with the sole purpose of delaying the entry of a competitor into the market. We are not aware of a case targeting this conduct being reviewed by CADE.

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

The Brazilian Research-Based Pharmaceutical Manufacturers Association Code of Conduct sets forth transparency clauses with regard to relationships (section 1.1.5), contracts (section 3) and donations (section 12) in the pharmaceutical sector. Clinical trials are also experiencing growth in Brazil and are contributing to the development of scientific research in Latin America.

The increased transparency granted by these measures does make it more likely for anticompetitive exchanges of information to occur. We are not aware of a case targeting a similar conduct being reviewed by CADE.

Anticompetitive unilateral conduct

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

Conducts carried out by a firm with monopoly or market power will be considered anticompetitive if they 'have as [their] object or effect':

- the limitation, restraint or, in any way, harm to open competition or free enterprise;
- control over a relevant market for a certain good or service;
- an increase in profits on a discretionary basis; or
- engagement in market abuse.

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

The Competition Law provides that a dominant position is presumed when 'a company or group of companies' controls 20 per cent of a relevant market. Article 36 further provides that CADE may change the 20 per cent threshold 'for specific sectors of the economy', but the agency has not formally done so to date. Such an assumption provides some guidance to private parties as it would be unlikely for CADE to find a violation in the absence of market power.

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

Yes. This would be the case of a valid patent that is related to a product that has no or few substitutes in the market.

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

The application for the grant or enforcement of a patent will not, by itself, expose the patent owner to antitrust liability. However, a patent owner may be found liable if it uses its patent right in an abusive manner, resulting in at least one of the effects listed in article 36 of the Competition Law (see question 17).

In 2007, Pró Genéricos filed a complaint against Eli Lilly do Brasil and Eli Lilly and Company for allegedly abusing their rights regarding Gemzar, a drug to treat cancer, to prevent generics entry. Among other alleged practices, Eli Lilly filed six different claims before the judicial courts to enforce its rights and required one additional five-year period of exclusive marketing rights given the discovery of a new use for the drug. An injunction ensured an additional protection for eight months, and for three months the pharmaceutical company Sandoz was not allowed to offer the competing drug Gemcit in the market.

In June 2015, CADE's tribunal found that Eli Lilly abused its rights by presenting misleading information to courts, with 'serious harm to public health and economy'. According to the agency, the drug maker did not clearly explain before courts that the request for a patent was never granted, an omission that was considered to be strategic and malicious, enabling the company to exclude competitors from the market. According to the Reporting-Commissioner, 'the company behaved in an anticompetitive manner by presenting multiple claims before several courts, omitting information to obtain artificially the monopoly in the sale of the medicine, besides unduly obtaining an exclusive right to sell the drug.'

CADE imposed a fine of 36.6 million reais. When calculating the fine, CADE doubled the expected fine in view of recidivism considering Eli Lilly's sanction in the alleged cartel against generic drugs (Administrative Process No. 08012.011508/2007-91).

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

Life-cycle management will not, by itself, expose the patent owner to antitrust liability. However, a patent owner may be found liable if this management comprises the use of the patent right in an abusive manner, resulting in at least one of the effects established in article 36 of the Competition Law (see question 17).

In 2008, Pró Genéricos, a local generic manufacturers association, filed a complaint against Abbott for allegedly abusing its power through patent violation claims against Cristália Produtos Químicos e Farmacêuticos regarding anaesthetics and the launch of a new antiviral drug that was not considered to be an improvement over the original drug (Administrative Inquiry No. 08012.011615/2008-08). The investigation is pending.

Furthermore, in 2011, Pró Genéricos filed a complaint against AstraZeneca for allegedly abusing its rights as a consequence of patent violation claims against Germed/Brazil's FDA regarding a number of blockbuster drugs, namely Crestor (cholesterol drug), Nexium (acid reflux relief drug) and Seroquel (drug for schizophrenia, bipolar disorder and major depressive disorder). AstraZeneca was accused of engaging in ring-fencing practices regarding its IP holdings to deter generic entry, as well as sham litigation practices before courts. The investigation is pending.

Update and trends

CADE's case law in the pharmaceutical sector is not straightforward; cases have a complex set of facts that make it difficult to extract a safe-harbour rule. The pending cases provide a unique opportunity for CADE to shed light on when business practices in the pharmaceutical sector can amount to an antitrust violation.

Market players need to take into account three aspects when devising their life cycle management strategies regarding products offered in Brazil. The first is that the association of generic drug makers is very active in Brazil and has been bringing a significant number of complaints before CADE since 2007. The second aspect is that CADE is understaffed and investigations generally last for over five years. This means that even when there is no violation, an investigation could be before the agency for numerous years, with all the associated uncertainty and costs; for example, the case against Aventis Pharma, which took eight years to be finally dismissed by CADE in 2013. The final aspect is that CADE has been extremely aggressive when sanctioning anticompetitive conduct, not limiting the sanctions to severe fines but also prohibiting sanctioned parties from benefiting from tax incentives, for example. The combination of those three aspects requires market players in Brazil to be extra-cautious.

Apart from targeting sham litigation and life-cycle strategies more generally, CADE has been devoting resources to the fight against bid rigging in the pharmaceutical sector, and we can expect the agency to bring new investigations in the near future.

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

No. Generic drugs may only be registered with ANVISA when the patent expires or is totally withdrawn by the patent holders. Individual licensing agreements or a decision by the owner of the patent to manufacture a generic drug is not sufficient to obtain the regulatory approval.

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

For conducts examined under the rule of reason, for which CADE undertakes detailed market analysis, including assessment of market shares, market structures and other economic factors, specific features of the pharmaceutical sector could provide an objective justification for the conduct.

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

Not applicable.

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

Generally, foreign investment must conform to the national industrial policies. The Guideline Catalogue of Foreign Investment Industries (revised in 2015) (Catalogue of Foreign Investment) provides the entry requirement for foreign investment in various industries. The Catalogue of Foreign Investment divides specific industries into 'encouraged', 'restricted' and 'prohibited' categories. Those that are not listed in the Catalogue of Foreign Investment generally are permitted industries. Before the Catalogue of Foreign Investment was revised in 2015, pharmaceutical manufacturing sectors fall into all three categories mentioned above. In the most recent Catalogue of Foreign Investment, however, the whole sector of pharmaceutical manufacturing was removed from the 'restricted' category. Nevertheless, the implementation of the processing measures of ready-for-use traditional Chinese medicines and the manufacturing of traditional Chinese patent medicine of secret prescriptions is still listed in the 'prohibited'ß category.

Meanwhile, the Drug Administration Law (amended in 2015) and Measures for Administration of Drug Registration (Registration Measures) together with other specific regulations, such as the Regulations for Implementation of the Drug Administration Law of the People's Republic of China, set out rules on the authorisation, registration and pricing of pharmaceutical products.

On 24 April 2015, the 14th Session of the Standing Committee of the 12th National People's Congress adopted the decision to amend the Drug Administration Law. The amendment not only simplified the procedures for the registration, modification, and cancellation of the drug manufacturing licence and drug distribution licence at the administration for industry and commerce, but also removed the price restrictions for most drugs to pave the way for the marketisation of drug prices. Article 7 of the current Drug Administration Law requires pharmaceutical producers to obtain production permits from the local food and drug administration (local FDA) where the producers are located. The permit is valid for five years and can be renewed provided that the application for renewal is approved.

According to articles 11 and 12 of the Drug Administration Law, wholesale and retail pharmaceutical distributors need to obtain the drug distribution licence issued by a local FDA before operating the relevant business. The drug distribution licence is also valid for five years and can be renewed upon application.

In addition, pursuant to Registration Measures, registration is required for clinical trials, production, and importation of pharmaceutical products in China. The China Food and Drug Administration (CFDA) issues registration codes, imported pharmaceutical products' registration certificates or medical and pharmaceutical products' registration certificates. Certificates are valid for five years and can be re-registered provided that the application for re-registration is approved.

As for pricing of drugs, article 55 of the Drug Administration Law states that business operators shall observe the regulations stipulated by the responsible department of price control of the State Council (ie, the National Development and Reform Commission (NDRC)). On 4 May 2015, the NDRC published an announcement on issuing the Opinions on Promoting Drug Pricing Reform (Fa Gai Jia Ge [2015] No. 904), which requires the removal of government pricing controls for most drugs (with the exception of narcotics and type I psychotropic drugs) from 1 June 2015. The government no longer administrates drugs by fixing maximum retail prices. Instead, the prices of drugs will be formulated by the market through different means according to the principle of administration by classification. On the same day, the NDRC published the Notice regarding Strengthening the Supervision and Administration on Pricing of Drugs (Fa Gai Jia Ge [2015] No. 930), which also contains specific regulations on pricing of drugs.

For the bodies that are entrusted with enforcing these rules, the CFDA and local FDAs are the primary agencies responsible for drug supervision. These are the agencies that issue drug registration certificates, distribution licences, and manufacturing licences and that conduct inspections to ensure that drugs meet quality standards. The CFDA is in charge of managing and supervising issues related to drugs at the national level while the local FDAs are in charge of the supervision and management of drugs in their respective geographic areas.

The State Council and provincial-level governmental departments also play a role in the overall supervision and promulgation of policy regarding drug distribution. The State Council is responsible for the overall supervision and management of drug-related work at the national level. Provincial-level governmental departments are responsible for the overall supervision and management of drug-related work in their respective geographic areas.

The State Administration of Industry and Commerce (SAIC) and its local bureaus, which supervise market operations in China, may also regulate drug distribution at various levels because drugs are considered commercial products.

In addition, the NDRC and local DRCs are in charge of supervising the enforcement of regulations on the pricing of drugs as well as other goods.

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

Yes. In China there are two main pieces of legislation on drugs distribution, which are the Provisions for Supervision of Drug Distribution (PSDD) and Quality Management Practice for Drug Operation (also known as Pharmaceutical Good Supply Practice) (GSP). The PSDD and GSP are formulated under the Drug Administration Law and Registration Measures and apply to drug wholesale, retail, storage and transportation. Besides the above, the Measures for the Classified Administration of Prescription Drugs and Over-the-Counter Drugs also provide some guidelines on distribution of pharmaceutical products. For medical devices, there is one main piece of legislation regulating the distribution, the Measures for the Supervision and Management of Medical Device Operation, which applies to the wholesale, retail, storage and transportation of medical devices.

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

None of the provisions of those legislations are directly relevant to the application of competition law to the pharmaceutical sector.

Competition legislation and regulation

4 Which legislation sets out competition law?

The Chinese Antimonopoly Law (AML) took effect on 1 August 2008. The AML was enacted for the purpose of preventing and restraining monopolistic practices, protecting fair competition in the market, enhancing economic efficiencies, safeguarding the interests of consumers and of the public at large, and promoting the robust development of the socialist market economy. It mainly regulates the following three monopolistic practices: monopoly agreements entered into by business operators; abuse of dominant market positions by business operators; and concentrations of business operators that exclude or limit competition or might exclude or limit competition. The AML also regulates administrative monopoly.

Before the enactment of the AML, the Anti-Unfair Competition Law and the Price Law provided the regulations on anti-unfair competition practices and price-related monopolistic practices.

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

The Ministry of Commerce (MOFCOM) is responsible for reviewing notification of concentrations of undertakings that have triggered certain turnover thresholds. The NDRC is responsible for price-related monopoly agreements, abuse of dominance and administrative monopolies, whereas the SAIC is responsible for non-price-related monopoly conduct.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

Normally, remedies can be imposed in merger controls as well as for abuse of dominance and monopoly agreements prohibited by the AML.

In the context of merger controls, as of 6 February 2017, out of 28 conditionally cleared transactions and two forbidden transactions, five relate to the pharmaceutical and medical device industry: the acquisition of Wyeth by Pfizer, the acquisition of Alcon by Novartis, the acquisition of Gambro by Baxter, the acquisition of Life Technology by Thermo Fisher Scientific, and the acquisition of St Jude by Abbott.

Structural remedies were used in the *Pfizer/Wyeth* case, where Pfizer was required to divest from the swine MH vaccine business under the brands of Respisure and Respisure One in China. Behavioural remedies were applied in the *Novartis/Alcon* case, such as the commitment of the termination of the sales regarding certain pharmaceutical products and the termination of the distribution agreement regarding certain lens-care products. Both structural and behavioural remedies were imposed in the *Baxter/Gambro* case, where Baxter was required to divest its global continual renal replacement therapy (CRRT) business, including all tangible and intangible assets necessary for the viability and competitiveness of the divested assets, and completely terminate its original equipment manufacturing (OEM) production agreement with Nipro regarding HD within China territory by 31 March 2016.

Similarly, both structural and behavioural remedies were applied in the *Thermo Fisher/Life Technology* case where Thermo Fisher was required to:

- divest its global cell-culture businesses, including the tangible and intangible assets necessary for the divested business's viability, marketability and competitiveness;
- sell its 51 per cent stake in Lanzhou National HyClone Bioengineering in China;
- divest its gene-modulation business, including the tangible and intangible assets necessary for the divested business's viability, marketability and competitiveness;
- offer a 1 per cent reduction in the catalogue prices of SDS-PAGE protein standard product and SSP reagent kit in the Chinese market every year for the next 10 years, and pledge to not reduce the discounts offered to Chinese distributors; and
- in the next 10 years, provide SSP reagent kits and SDS-PAGE protein standard products to third parties by way of OEM agreement, or grant third-party perpetual and non-exclusive technology licences as relating to those two products, whichever is chosen by the third party.

In the *Abbott/St Jude case*, structural remedies were applied, such as the divesture of the small hole vessel closure device business to Terumo, provision of transitional service, and finishing the divesture within 20 days of closing the *Abbott/St Jude* transaction.

Besides the above, Shanghai Fosun Pharmaceutical and Dade Holding Co, Ltd were fined 200,000 yuan and 150,000 yuan respectively for their failure to submit a merger filing prior to Fosun's acquisition of a 35 per cent stake in Suzhou Erye Pharmaceutical and Dade's acquisition of a 50 per cent stake in Jilin Sichang Pharmaceutical Company.

In addition, the NDRC and SAIC have conducted several investigations on pharmaceutical companies on abuse of dominance and engaging in monopoly agreements. Remedies were imposed in some of the penalty decisions.

For example, in November 2011, the NDRC announced its decision to fine two private pharmaceutical companies nearly 7 million yuan for violating the AML by abuse of dominant position. The penalised companies are both pharmaceutical distribution companies that sell a key ingredient for a drug that cures hypertension. According to the NDRC, the pharmaceutical companies entered into exclusive sales agreements with the only two manufacturers of the ingredient in June 2011 and thereby gained full control of the domestic supply of the key ingredient. Both of them then raised the sales price of the ingredient significantly and required the downstream medicine manufacturers to raise their prices as well. As a result, the downstream medicine manufacturers could not afford the excessively high cost of raw material and were forced to suspend production, causing a shortage of supply of the downstream pharmaceutical product in the market. Upon receipt of complaints from these medicine manufacturers, the NDRC initiated investigations and imposed fines on the companies. In addition, the NDRC also ordered the companies to terminate their exclusive sales agreements with the ingredient producers.

For engaging monopoly agreements, on 28 January 2016, the NDRC stated that it has fined five domestic pharmaceutical companies almost 4 million yuan for reaching and implementing monopoly agreements on the sales of allopurinol ingredients. The five companies, Chongqing Qingyang Pharmaceutical and its distributor Chongqing Datong, the Place Pharmaceutical Jiangsu, and Shanghai SINE Pharmaceutical and its distributor Shangqiu Huajie, held four meetings on the distribution of allopurinol in the period between April 2014 and September 2015 and reached monopoly agreements on:

- fixing and raising the price of allopurinol;
- dividing markets for sales of allopurinol; and
- reaching an agreement on bidding in different areas.

The NDRC has requested that the companies terminate their illegal behaviour immediately.

Moreover, on 22 December 2015, the Chongqing municipal branch of the SAIC fined Chongqing Qingyang Pharmaceuticals 439,300 yuan, or 3 per cent of its 2013 revenue, for abuse of market dominance. An investigation found that Qingyang Pharmaceuticals had stopped supplying allopurinol ingredients to its distributors and other manufacturers of allopurinol for half a year in order to raise the prices of the ingredients and increase its share of the allopurinol market.

On 22 July 2016, the NDRC published its decisions to fine three domestic pharmaceutical companies 2,603,823 yuan in total for reaching and implementing monopoly agreements on the sales of estazolam active pharmaceutical ingredients (APIs) and tablets. The three companies, Huazhong Pharmaceutical, Shandong Xinyi Pharmaceutical, and Changzhou Siyao Pharmacy reached monopoly agreements on:

- entering into and implementing monopoly agreements to jointly boycott transactions of estazolam APIs; and
- entering into and implementing monopoly agreements to fix or change prices of estazolam tablets.

The NDRC has requested that the companies terminate their illegal behaviour immediately.

On 7 December 2016, the NDRC announced its decision to fine Medtronic (Shanghai) Management 118.5 million yuan for engaging in and implementing resale price maintenance (RPM) arrangement for medical equipment supplies. Medtronic restricted the minimum RPM, minimum bid prices of distributors, and minimum RPM for hospitals.

On 29 December 2016, the Shanghai Price Bureau fined Smith & Nephew (a British medical equipment company) 742,148 yuan for

engaging in RPM. Smith & Nephew and its distributors entered into and implemented RPM agreement for over-the-counter (OTC) CICA-CARE silicone gel sheets for scar treatment in the Chinese market between 2014 and October 2015, and Smith & Nephew asked online pharmacies to sell its products at or above certain price floors since 2014.

On 24 November 2016, the Chongqing AIC announced its decision to fine Chongqing Southwest No.2 Pharmaceutical Factory 17,240 yuan for abusing its dominance by refusal-to-deal. The company is a manufacturer of phenol APIs, which are non-substitutable in the manufacture of certain drugs, such as salicylic acid and phenol plasters, a product for curing clavus. The company refused to supply to parties other than Henan Shangqiu Xinxianfeng Pharmaceutical.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

In accordance with article 50 of the AML, business operators who practise monopoly conduct, causing others to suffer losses therefrom, shall bear civil liability pursuant to the law.

To provide more guidance on AML civil actions, China's Supreme People's Court issued the Rules of the Supreme People's Court on Several Issues Concerning the Application of Law in Hearing Civil Cases Caused by Monopolistic Conduct (the Rules) on 3 May 2012. The Rules contain 16 articles covering the standing of plaintiffs, jurisdiction, burden of proof, evidentiary rules, expert witness, the judicial process, form of civil liabilities and the statute of limitations. The Rules entered into force on 1 June 2012.

According to the Rules, where a defendant's monopolistic conduct has caused any losses to the plaintiff, the people's court may, in light of the plaintiff's claims and the finding of facts, order the defendant to cease infringement, compensate for losses, and otherwise assume civil liability in accordance with the law. The people's court may also, upon the petition of the plaintiff, include the plaintiff's reasonable expenses for investigation and prevention of the monopolistic conduct in the scope of compensation for losses.

In May 2012, the Shanghai First Intermediate People's Court rendered judgment on the vertical monopoly agreement action filed by Beijing Rainbow (a pharmaceutical equipment company in Beijing) against Johnson & Johnson (J&J). Beijing Rainbow alleged that J&J engaged in resale price maintenance (RPM) that led to the elimination or restriction of competition in the relevant market and claimed damages of 14.4 million yuan. The court found that the distribution agreement did fix prices, but that that alone was not sufficient for the plaintiff to prove that competition had been restricted. On this basis the court rendered its judgment in favour of J&J. Beijing Rainbow appealed to the Shanghai Higher People's Court on 28 May 2012. On 1 August 2013, after three court hearings, the Shanghai High Court reversed the lower court decision and ruled that J&J had violated the AML by having RPM agreements with Beijing Rainbow, and that J&J should compensate Beijing Rainbow 530,000 yuan for the economic loss that resulted from the RPM agreement.

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

In merger filing cases, it is a routine process for MOFCOM to conduct inquiries into certain stakeholders, such as the industry association, before it makes the final decision on the filing. For pharmaceutical filings, MOFCOM will conduct the sector-wide inquiries via the industry association or other competent authorities in charge of the industry. The feedback from these inquiries may influence the outcome of the merger filing to some extent.

Meanwhile, according to news reports, from mid-2013 to the end of 2015, the NDRC launched several rounds of inquiry focusing on the pricing of pharmaceutical products and medical devices in the form of a survey or questionnaire. In 2016, the NDRC further distributed two rounds of questionnaires to pharmaceutical companies, both of which focus on price monopoly. The first round was sent to thousands of pharmaceutical companies in May 2016, issued through NDRC's local branches, local price bureaus, and local price associations. The second round was started in August 2016 and was aimed at the companies that caught the agency's attention during the first round. Moreover, in June 2016, having noticed that there was some price-related illegal behaviour in the drug and API markets, which affected fair competition, increased the patients' burden and aroused objections from consumers and enterprises, the NDRC decided to initiate another round of national special inspection into drug prices. In particular, behaviours to be investigated and punished include:

- whether enterprises manufacturing and operating APIs or drugs reach and implement monopoly agreements, and whether industry associations organise relevant enterprises to reach and implement monopoly agreements; and
- whether enterprises manufacturing and operating APIs or drugs abuse dominant market position to sell APIs or drugs at an unfairly high price.

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

The Rules of the Supreme People's Court on Several Issues Concerning the Application of Law in Hearing Civil Cases Caused by Monopolistic Conduct is silent on whether NGOs, trade associations or consumer groups could bring private antitrust litigation on behalf of the plaintiff.

In the meantime, in accordance with article 55 of the Civil Procedure Law of the People's Republic of China (2012 Amendment), for conduct that pollutes the environment, infringes the lawful rights and interests of large numbers of consumers or otherwise damages the public interest, an authority or relevant organisation as prescribed by law may institute an action in a people's court. Therefore, NGOs or other non-government background organisations (which are not organised as prescribed by law) may not be able to launch a private action against infringers of the competition rules.

However, as mentioned in question 8, the opinions of the trade associations and consumer groups may influence the antitrust investigation conducted by the antitrust enforcement agencies.

Review of mergers

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

As mentioned in question 2, national regulatory restrictions apply on the production, importation, registration, pricing, and distribution and supply of the pharmaceutical products. So in the merger review, MOFCOM will take into consideration the influence of these sector-specific features.

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

In the pharmaceutical sector, there are many ways to classify and categorise pharmaceutical products. Anatomical therapeutic classification (ATC), which is developed and used by the European Pharmaceutical Marketing Research Association, and also by the World Health Organization, is normally recognised as the standard classification for the purpose of defining the relevant product market in the merger filing in China. Further, the third level of ATC classification (ATC-3) allows medicines to be grouped in terms of their therapeutic indications (ie, their intended use) and can therefore be used as an operational market definition. While there is no particular principle regarding market definition of medical device, substitution test is still applied.

In the public decision issued by MOFCOM on the conditional approval of the acquisition of Wyeth by Pfizer, MOFCOM acknowledged the market classification of ATC-3 in the human pharmaceutical sector. In the *Baxter/Gambro* case, MOFCOM determined the relevant markets were composed of CRRT monitors, CRRT dialysers and CRRT blood lines respectively.

MOFCOM has not published any market definition based on active pharmaceutical ingredients (APIs) and finished drugs. However, according to Chongqing AIC's decision on *Chongqing Qingyang Pharmaceuticals* in 2016, a separate market of APIs (ie, a market of allopurinol ingredients) was defined and assessed. It is likely that MOFCOM may also refer to this approach in the future.

Geographic markets are typically defined in the pharmaceutical sector as nationwide due to the national regulatory restrictions on production, importation, registration, pricing, and distribution and supply. This was borne out by the public decision issued by MOFCOM on the

conditional approval of Pfizer's acquisition of Wyeth. In the *Baxter/Gambro* case, it seems that MOFCOM has left the geographic market definition open as it analysed the market situation in both China and the global market. In the *Thermo Fisher/Life Technology* case, the MOFCOM defined the geographic market as China, while taking influence on the global market into consideration as well. In the *Abbott/St Jude* case, the MOFCOM defined the geographic market as China.

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

In the regime of merger filing, it is possible for the concentration parties to argue that the concentration can strengthen the local or regional research and development activities, or to bring efficiency-based arguments. Though it depends on MOFCOM's discretion whether this kind of argument could address the identified antitrust concerns, if the parties provide specific or quantifiable data regarding how the concentration would enhance efficiency, it would help MOFCOM assess and consider this kind of argument.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

MOFCOM has clearly stated that in merger review they will pay great attention to the combined market shares of the merging parties. Besides, before MOFCOM reaches a conclusion as to whether the transaction may have the effect of eliminating or restricting competition in the relevant market, MOFCOM will also comprehensively assess other factors, such as the general market situation, the difficulty of market entry and the demand and supply-side bargaining power. Among other things, severe competition concerns may arise when the merging parties account for a substantial combined market share in the highly concentrated relevant markets.

In addition, to achieve a comprehensive assessment of the competition status of the relevant market, MOFCOM always takes into consideration the potential competition from the new entries. For example, in the public decision issued by MOFCOM on the conditional approval of acquisition by Western Digital Corporation of Hitachi Global Storage Technologies Holdings Ltd, MOFCOM clearly stated that:

> *to reach a viable scale requires huge investments in production, R&D and market development, and thus poses huge potential risks. In the past decade, no new competitor has entered the market. Therefore, MOFCOM has found that entry into the HDD market is very difficult.*

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

In some previous filing cases, MOFCOM has taken account of the potential overlap of the parties' pipeline products when the overlap will account for a substantial combined market share and competition in the current market is fragile. However, there is currently no precedent for MOFCOM to impose their conditions due to competition concerns relating to products that are being developed.

As mentioned in question 13, potential competition is also taken into account when MOFCOM conducts merger reviews on transactions.

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

As mentioned in question 6, MOFCOM has imposed structural remedies, behavioural remedies or mixed remedies in previous conditional clearance decisions.

For example, in the *Baxter/Gambro* deal, MOFCOM required Baxter to divest its global continuous renal replacement therapy business including tangible and intangible assets required to guarantee the survival and competitive power of the divested business as a structural remedy. In addition, MOFCOM required Baxter to terminate the OEM agreement with Nipro within the territory of China before 31 March 2016 (contracts with customers or other supplier obligations under relevant laws that already exist at the time of MOFCOM's decision shall be excluded) as a behaviour remedy.

In addition, licensing arrangements have been accepted as a remedy in several different cases. For instance, in the *ARM/Giesecke & Devrient/Gemalto* case, MOFCOM required ARM to abide by the non-discrimination rule. It also required that in the future ARM will release the security monitoring code as well as other information of its TrustZone technology that is necessary to develop TEE solutions, including relevant licences, licensing standards and conditions. In the *Google/Motorola* case, MOFCOM requested that Google license the Android platform on a free and open basis, consistent with current business practice, in order to alleviate its concerns.

In addition, MOFCOM promulgated a new rule on the restrictive conditions of notifications of concentrations in December 2014, titled 'Interim Provisions for Imposing Restrictive Conditions on Business Concentrations', which takes into account the experiences of implementation of conditional remedies and provides the framework in relation to the determination, implementation, supervision, amendment, termination and legal liabilities of restrictive conditions. In the *Abbott/St Jude* case, the MOFCOM referred to article 20 of the *Interim Provisions for Imposing Restrictive Conditions on Business Concentrations* and required Abbott and St Jude to preserve the viability, competitiveness and marketability of the divested business.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

We have not come across any precedents in relation to the notification of the sole acquisition of patents or licences. However, if the acquired patents or licences could be deemed to be independent operable businesses or independent assets with contributable turnover that also meet the filing threshold, we cannot rule out the possibility of the notifiability of such acquisition.

Anticompetitive agreements

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

According to the AML, the term 'monopoly agreements' refers to the agreements, decisions or other concerted behaviour that may eliminate or restrict competition.

Article 13 of the AML prohibits horizontal agreements such as:

- fixing or changing the price of commodities;
- restricting the production quantity or sales volume of commodities;
- dividing the sales market or the raw material supply market;
- restricting the purchase of new technology or new facilities or the development of new technology or new products;
- jointly boycotting transactions; and
- other monopoly agreements as determined by the Antimonopoly Law Enforcement Agency under the State Council.

Article 14 of the AML prohibits vertical agreements such as:

- fixing the price of commodities for resale to a third party;
- restricting the minimum price of commodities for resale to a third party; and
- other monopoly agreements as determined by the Antimonopoly Law Enforcement Agency under the State Council.

Article 15 provides for the following exemptions for monopoly agreements:

- for improving technology, researching and developing new products;
- for upgrading the quality of products, reducing costs, improving efficiency, unifying the models and standards of the products, or implementing professional labour distribution;
- for improving the operational efficiency and enhancing the competitiveness of small and medium-sized business operators;
- for realising public interests of the society such as conservation of energy, protection of the environment, provision of disaster relief, etc;
- for mitigating a serious decrease in sales volume or excessive overstock from production during periods of recession;
- for protecting the legitimate interests during the process of conducting foreign trade and cooperation; and
- for other purposes as prescribed by the laws and the State Council.

To apply these exemptions from the above first five bullet points, the business operators shall also prove that the agreements reached will not seriously restrict competition in the relevant market and consumers will be able to share in these benefits.

18 To what extent are technology licensing agreements considered anticompetitive?

A technology licensing agreement is not considered an anticompetitive agreement by itself. However, if technology licensing agreements are combined with other types of agreements involving anticompetitive conduct set in articles 13, 14 and 17 of the AML, the technology licensing agreements might be deemed anticompetitive.

The SAIC has promulgated the Provisions on the Prohibition of Abuse of Intellectual Property Rights to Eliminate or Restrict Competition (SAIC IP Rules), which came into effect on 1 August 2015. According to article 4 of the SAIC IP Rules, business operators shall not make use of exercising IP rights to achieve a monopoly agreement that is prohibited by articles 13 and 14 of the AML. Article 6 of the SAIC IP Rules also prohibits business operators with market dominance from abusing market dominance in exercising intellectual property rights to eliminate or restrict competition. For licensing agreements that may be deemed unilateral conduct violations, see question 27.

Moreover, MOFCOM also considers whether technology licensing agreements are anticompetitive in merger reviews. For example, according to the conditional clearance decision made by MOFCOM with regard to the proposed establishment of a joint venture between General Electric and China Shenhua in November 2011, the technology licensing agreements (for coal-water slurry gasification technology) were taken into consideration as one of the important factors for the competitive assessment and the definition of product market to the merger control review.

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

Co-promotion and co-marketing agreements are not regarded as anticompetitive agreements by themselves. However, if the co-promotion and co-marketing are combined with price fixing, market division, resale price maintenance or other anticompetitive conduct set in articles 13 and 14 of the AML, the co-promotion and co-marketing agreements might be deemed anticompetitive. Moreover, if such activities facilitate information exchange between competitors, this information exchange may also be problematic.

According to news released by the SAIC, several investigations of monopoly agreement involving price-related or segmentation-related co-promotion or co-marketing agreements were closed by provincial AICs under the authorisation of the SAIC. In the new car insurance case in Hunan province, local insurance companies were found to reach into co-promotion, co-marketing agreement by assigning one company to sell the insurance as their agent and to segment the market and agree on the unified discount. This conduct was found to be in violation of the AML for entering into a horizontal monopoly agreement.

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

As mentioned above, article 13 of the AML lists prohibited horizontal agreements, such as price fixing, production or sales restriction, and market segmentation. There is a catch-all provision under article 13 giving the authorities the power to deem other horizontal agreements anticompetitive.

On 20 August 2014, the NDRC announced its decisions regarding investigations on a cartel between eight Japanese auto parts suppliers (Hitachi Ltd, Denso Corp, Asian Electric Co Ltd, Mitsubishi Electric Corp, Mitsuba Corp, Yazaki Corp, Furukawa Electric Co Ltd and Sumitomo Corp) and decisions regarding cartel investigations among four Japanese bearing suppliers (Nachi-Fujikoshi Corp, Seiko Holdings Corp, JTEKT Corp and NTN Corp). The NDRC found that from January 2000 to February 2010, the eight Japanese auto parts suppliers had held bilateral and multilateral meetings in order to establish multiple horizontal-pricing agreements that best served their own interests while eliminating competition. The NDRC also found that from 2000 to June 2011, the four Japanese bearing suppliers organised an Asian studies conference in Japan, as well as an export market meeting in Shanghai to discuss Asia and China market price policy, timing and magnitude of price appreciation, and implementation of price appreciation. In addition, the parties concerned implemented price appreciation in the sales of bearings in China based on the agreed price or the exchange of information regarding price appreciation during the Asian studies conference and the export market meeting. According to the NDRC's announcement, the eight Japanese auto parts suppliers were fined 831.96 million yuan in total and the four Japanese bearing suppliers were fined 403.44 million yuan in total for their AML-violating behaviour.

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

As provided in article 14 of the AML, business operators are prohibited from reaching an agreement with their trading parties that fixes the resale price or restricts the minimum resale price. There is also a catch-all provision under article 14 giving the authorities the power to find other vertical agreements that they consider to be anticompetitive.

On 22 February 2013, Guizhou Pricing Administration issued an official statement, imposing a fine of 247 million yuan on Moutai for fixing the minimum resale price of distributor, and Sichuan Provincial Development and Reform Commission also issued an official statement, imposing a fine of 202 million yuan on Wuliangye for similar RPM. This was the first case on vertical monopoly agreements, testing the NDRC's standard towards the identification of RPM conducts (ie, the assessment of anticompetitive effects of RPM and the damage to consumers' interests).

After the *Moutai* case, more and more investigations and decisions on vertical agreements have been made by the antitrust authorities. For example, the Guangdong DRC started an investigation in August 2014 into Dongfeng-Nissan and found that between April 2012 and July 2014, Dongfeng-Nissan imposed vertical controls on its dealers by issuing business policies, price control methods and assessment measures to strictly control all prices. On 10 September 2015, Guangdong DRC announced the result of the investigation and held that Dongfeng-Nissan violated article 14 of the AML by imposing resale price maintenance agreements and restricting market competition. In 2016, the NDRC investigated and punished the companies for vertical agreements of RPM in the *Medtronic* case and the *Smith & Nephew* case. See question 6.

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

Currently, we have not yet noticed any precedents with regard to potential antitrust violation in the settlement of a patent dispute. That said, as mentioned in question 18, business operators shall not make use of exercise of IP rights, including by means of reaching settlements of patent disputes, to establish monopoly agreements that are prohibited by articles 13 and 14 of the AML.

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

We are not aware of any precedents in China where anticompetitive exchanges of information occur in the pharmaceutical sector because of increased transparency. However, it would be problematic if business operators exchanged sensitive competition information to engage in monopoly agreements or concerted conduct prohibited by the AML. Typically, sensitive information includes information on price, capacity, cost structure, future plans for pricing and capacity, and target customers.

Anticompetitive unilateral conduct

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

According to article 17 of the AML, business operators with a dominant market position are prohibited from committing any of the following acts:

- selling products at unfairly high prices or buying products at unfairly low prices;
- selling products at prices below cost without any justifiable cause;

- refusing to trade with a trading party without any justifiable cause;
- restricting their trading party so that it may conduct deals exclusively with themselves or with designated business operators without any justifiable cause;
- implementing tie-in sales or imposing other unreasonable trading conditions at the time of trading without any justifiable cause;
- applying discriminatory treatments on trading prices or other trading conditions to their trading parties with equal standing without any justifiable cause; or
- other forms of abusing the dominant market position as determined by the Antimonopoly Law Enforcement Agency under the State Council.

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

According to the AML, the term 'dominant market position' refers to a market position held by business operators that have the ability to control the price or quantity of commodities or other trading conditions in the relevant market, or block or affect the entry of other business operators into the relevant market. The AML provides several factors for evaluating monopoly power:

- the market share of the business operator in the relevant market and the competition status in the relevant market;
- the ability of the business operator to control the sale market or the procurement market for raw materials;
- the financial strength and technological capabilities of the business operator;
- the extent of reliance by other business operators on transactions with the business operator;
- the level of ease or difficulty for entry by other business operators into the relevant market; and
- any other factors relating to the determination of dominant market position of the business operator.

According to article 19 of the AML, under any of the following circumstances, a business operator may be presumed to have a dominant market position:

- the market share of one business operator accounts for half or more of the relevant market;
- the joint market share of two business operators accounts for two-thirds or more of the relevant market; or
- the joint market share of three business operators accounts for three-quarters or more of the relevant market.

Nevertheless, the above presumptions are rebuttable. In addition, when establishing joint dominance, if any of the business operators has a market share of less than 10 per cent, that business operator shall not be considered to have a dominant market position.

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

A patent holder will not be deemed a dominant business operator simply on account of the patent that it holds. According to article 6 of the SAIC IP Rules, a business operator holding IP rights may constitute one of the factors for ascertainment of its market dominance, but the presumption of the business operator's market dominance in the relevant markets shall not be merely based on the IP rights held by the business operator.

Similarly, the draft IP antitrust guidelines, promulgated and released by the NDRC and the SAIC respectively, also recognise that the IP holders should not be presumed to have the dominant market position solely due to their possession of the IP rights. The Anti-monopoly Commission under the State Council is now consolidating the draft IP antitrust guidelines and is expected to issue the finalised guideline in this year.

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

Article 55 of the AML provides that:

> *this law shall not apply to the conduct of operators exercising their intellectual property rights in accordance with the laws and relevant administrative regulations on intellectual property rights; however, this law shall apply to the conduct of operators seeking to eliminate or restrict market competition by abusing their intellectual property rights.*

This is the only provision under the AML that directly addresses the tension between the exercise of IP rights and the protection of competition.

To make article 55 more practical, the SAIC has promulgated the SAIC IP Rules, which prohibit operators engaging in conducts described under article 17 of the AML (see question 24). In addition, article 10 of the SAIC IP Rules specifies that business operators with market dominance will be deemed to be adding unreasonable terms to the transaction if they add the following restrictions or conditions, in the course of implementing intellectual property rights, without reasonable justification:

- the requirement of exclusive grant-back of techniques improved by the transaction counterparties;
- the prohibition of transaction counterparties from questioning the validity of their intellectual property rights;
- the restriction of the transaction counterparties from making use of competing commodities or techniques upon expiry of the licensing period without infringing upon the intellectual property rights;
- the continuation to exercise intellectual property rights for which the protection period has expired or been declared void;
- the prohibition of transaction counterparties from entering into transactions with third parties; or
- the imposition of any other unreasonable restrictive conditions on the transaction counterparties.

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Moreover, according to the SAIC IP Rules, refusal to license certain IP rights may also be found to be problematic if the IP right is deemed an essential facility or after the IP has become an essential patent for a standard.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

We are unaware of any precedent in the pharmaceutical sector. However as mentioned above, business operators shall not exercise IP rights to establish monopoly agreements that are prohibited by articles 13 and 14 of the AML. Business operators with market dominance are also prohibited from abusing market dominance in exercising intellectual property rights to eliminate or restrict competition.

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

To the best of our knowledge, we are not aware of any prohibitions against a patent holder's right to 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.

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

Due to the lack of rules and precedents, it is not clear if the specific features of the pharmaceutical sector may provide an objective justification for conduct that may otherwise infringe antitrust rules.

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

Not applicable.

European Union

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

European Union (EU) legislation concerning pharmaceutical products comprises a large body of Regulations, which have direct effect in all 28 EU member states, and Directives, which are transposed into national law by the EU member states. The core legislation relating to the marketing, authorisation and pricing of pharmaceutical products in the EU includes the following:

- Directive 2001/83/EC, establishing the requirements and procedures governing the marketing authorisation for medicinal products for human use, as well as the rules for the constant supervision of products following authorisation. This Directive has been amended several times, most recently by Directive 2012/26/EU regarding pharmacovigilance, and the Falsified Medicines Directive 2011/62/EU;
- Regulation (EC) 726/2004, as amended, establishing procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human and veterinary use and establishing the European Medicines Agency;
- Regulation (EC) 469/2009, establishing the requirements necessary to obtain a Supplementary Protection Certificate, which extends the period of patent protection applicable to medicinal products at the EU-level;
- Directive 89/105/EEC, ensuring the transparency of measures taken by EU member states to set the prices and reimbursements of medicinal products. Specifically, while each EU member state has competence over the pricing and reimbursement of medicines for human use, they must also comply with this Directive, which establishes procedures to ensure that member state decisions and policies do not obstruct trade in medicinal products. The European Commission (the Commission) proposed to repeal and replace Directive 89/105/EEC, but this proposal was withdrawn in 2015; and
- Directive 2003/94/EC laying down the principles of good manufacturing practice in respect of medicinal products and investigational medicinal products for human use.

As regards the relevant enforcement bodies, the European regulatory system consists of a network of regulatory authorities from the 31 EEA member states, the Commission and the European Medicines Agency (EMA). Before a medicine can be placed on the market, it must be authorised either at the EU or national level. The EMA is responsible for medicines that are managed through the central authorisation procedure, whereby a single authorisation may be granted for use throughout the EU. Medicines not falling within the centralised procedure are authorised by national competent authorities. National authorities also take responsibility for granting licences to manufacturers, importers and distributors of medicines.

EMA and national competent authorities are also responsible for ensuring compliance with the legal requirements governing medicinal products (article 111(1) of Directive 2001/83/EC; see also article 15(1) of Directive 2001/20/EC). To this end, the authorities may conduct inspections (including unannounced inspections) or order that tests on samples be carried out. Regulatory rules are enforced, and breaches prosecuted, by national authorities.

Finally, the Commission ensures that EU laws are applied in the national systems of the EU member states by monitoring the implementation and transposition of EU legislation.

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

Rules concerning the wholesale distribution and brokering of pharmaceutical products are harmonised at the EU level under Directive 2001/83/EC, as amended (Title VII, articles 76 to 85b). This includes rules regarding the sale of medicines at a distance to the public (Title VIII, articles 85c and 85d). This Directive is supplemented by Guidelines on good distribution practice of medicinal products for human use (2013) and Guidelines on good distribution practice of active substances for medicinal products for human use (2015).

In contrast, rules concerning the retail sale of medicinal products vary to a greater degree among the national laws of the EU member states.

Notably, the Court of Justice of the European Union (CJEU) ruled that retail-licensed pharmacists who are also authorised to engage in the wholesale distribution of medicinal products under national law must also ensure compliance with Directive 2001/83/EC. See Case C-7/11 *Criminal proceedings against Fabio Caronna* (decision of 28 June 2012).

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

Several aspects of EU (or national) legislation concerning pharmaceuticals are relevant to the application of competition law.

For example, pharmaceutical companies have obligations to ensure an appropriate and continued supply of medicines in the domestic market (eg, article 81 of Directive 2001/83/EC). Under competition law, however, companies may infringe articles 101 or 102 of the Treaty on the Functioning of the European Union (TFEU) if they engage in unjustified strategies to restrict parallel trade. The legislative requirement to ensure a minimum supply on the national market, however, may not justify a dominant pharmaceutical company from refusing to supply ordinary wholesale orders (eg, C-468-478/06 *Lelos and others* (2008); C-501/06 P *GlaxoSmithKline Services v Commission* (2009)).

Efforts to restrict or delay entry of generic pharmaceuticals following the expiration of patent protection may also infringe articles 101 or 102 TFEU (eg, C-457/10 P *AstraZeneca* (2012); T-472/13 *Lundbeck* (2016)).

Competition legislation and regulation

4 Which legislation sets out competition law?

The basic provisions of EU competition law are contained in the TFEU:

- article 101(1) TFEU prohibits anticompetitive agreements and concerted practices. Article 101(3) TFEU, however, provides an exemption from article 101(1) if the conduct at issue:
  - generates efficiencies, for which consumers receive a fair share;
  - is indispensable to attaining these efficiencies; and
  - does not eliminate competition;

- article 102 TFEU prohibits the abuse of a dominant position;
- article 106 TFEU provides that, in the case of public undertakings (ie, businesses) or businesses with special or exclusive rights, member states may not enact or maintain any measure contrary to the EU Treaties, but there are some exceptions; and
- article 107(1) TFEU prohibits EU member states from granting aid to undertakings that distorts, or threatens to distort, competition and trade between member states, but there are some exceptions.

In addition to the provisions of the TFEU, EU competition law is furthermore governed by certain Regulations, including:

- Regulation No. 139/2004 on the control of concentrations between undertakings (EUMR);
- Council Regulation (EC) No. 1/2003 on the implementation of the rules on competition laid down in articles 81 and 82 of the Treaty; and
- Commission Regulation (EC) No. 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to articles 81 and 82 of the EC Treaty.

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

Mergers

The EUMR applies to all 'concentrations' with a 'Community dimension', including those in the pharmaceutical sector. This means that the Commission has jurisdiction to review and approve or prohibit 'concentrations' (ie, mergers, acquisitions, certain joint ventures and other transactions resulting in a change of control over another undertaking) that meet certain turnover-based thresholds and thus have a 'community dimension'. Transactions meeting the jurisdictional criteria of the EUMR must be notified to the Commission and they cannot be completed until they are approved by the Commission. Transactions not meeting these criteria may be subject to review in one or more EU member states, depending on whether national jurisdictional thresholds are satisfied.

Alongside these general rules, the EUMR provides for the referral of transactions between the Commission and national competition authorities (NCAs) in certain cases, provided certain criteria are met. Transactions subject to the Commission's jurisdiction can be referred to one or more NCAs (article 4(4) and article 9 EUMR). Conversely, parties to a transaction that is notifiable in three or more EU member states (but does not fulfil the EUMR's jurisdictional requirements) can voluntarily ask the Commission to review the transaction (article 4(5) EUMR). Finally, one or more NCAs can ask the Commission to review a transaction that does not fulfil the EUMR's jurisdictional requirements if certain criteria are met (article 22).

Anticompetitive agreements and conduct

The principal authority responsible for the enforcement of competition law in the EU is the Commission, including for the pharmaceutical sector. However, pursuant to Regulation (EC) 1/2003, the Commission, NCAs and national courts are all empowered to apply articles 101 and 102 TFEU to alleged anticompetitive agreements or abuses of a dominant position. The Commission and the NCAs use the European Competition Network to coordinate investigations.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

Regulation (EC) 1/2003 sets out the remedies and penalties that the Commission can impose for infringements of articles 101 and 102 TFEU. Of note are the following:

- under article 7 of Regulation (EC) 1/2003, if the Commission finds an infringement of articles 101 or 102 TFEU, it can require the companies involved to end the infringement. The Commission can also impose structural or behavioural remedies, but only where there is no equally effective remedy or where an equally effective remedy would be even more burdensome;
- in urgent cases, article 8 of Regulation (EC) 1/2003 enables the Commission to order interim measures based on a prima facie finding of infringement if there is a risk of serious and irreparable harm to competition;
- article 9 of Regulation (EC) 1/2003 enables a company to propose commitments to address the Commission's concerns. If they are accepted by the Commission, the Commission will issue a decision making the commitments legally binding for a period of time (without a formal finding of infringement); and
- article 23 of Regulation (EC) 1/2003 enables the Commission to impose fines on the companies involved of up to 10 per cent of a company's annual turnover in the preceding business year. The Commission can impose daily penalties of up to 5 per cent of a company's average daily turnover in the event that a company does not comply with a prohibition order, interim measure or commitment.

In recent years, the Commission has imposed high fines on pharmaceutical companies for infringements of EU competition law. For instance, in 2014, the Commission imposed fines totalling €427.7 million on Servier and a number of generic drug manufacturers for using reverse payment patent settlement agreements to delay the entry of a generic version of perindopril, in violation of articles 101 and 102 TFEU. This followed two cases in 2013 in which the Commission imposed fines of €145 million on Lundbeck and a group of generic companies, and a fine of €16.3 million on Johnson & Johnson and Novartis – also for delaying market entry of generic versions of branded pharmaceuticals. Notably, the Commission's 2013 decision in *Lundbeck*, including the imposition of the fine, was upheld by the General Court in 2016.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Under EU law, every individual and company has a right to compensation for harm caused by any infringement of EU competition law (Case C-453/99 *Courage v Crehan*). Claimants may bring actions for damages before national courts either on a stand-alone basis or following on from a public authority decision. This right to full compensation is now enshrined in Directive 2014/104/EU (the Antitrust Damages Directive), which was formally adopted on 10 November 2014 and signed into law on 26 November 2014. The Antitrust Damages Directive is intended to harmonise certain procedures across the EU for claimants seeking to bring actions for damages resulting from anticompetitive conduct or agreements. Private parties can, in principle, also seek injunctive relief.

By way of example, in 2011, the UK government brought an action in a UK court against Servier for allegedly delaying rivals from launching generic versions of perindopril, claiming €246 million in damages based on the alleged overcharge paid for the drug during the period following patent expiry to the introduction of the first generic. The UK government's claim was issued after the Commission announced that it was investigating Servier and others for alleged 'pay for delay' agreements, but before the Commission imposed fines on these companies in 2014. The UK case is ongoing.

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

Under article 17 of Regulation (EC) 1/2003, the Commission can – on its own initiative – conduct sector-wide inquiries into a particular industry or into a particular type of agreement across various sectors of the economy. In doing so, the regulator may request or require companies or associations concerned to supply detailed information or carry out on-site inspections.

In 2008, the Commission initiated an extensive inquiry (involving on-site inspections of originator and generic pharmaceutical companies) into possible anticompetitive practices in the pharmaceutical sector. The inquiry was completed in 2009, when the Commission issued a Final Report. The Final Report principally concluded that as a consequence of, inter alia, company practices:

- market entry of generic drugs is delayed;
- not enough innovative medicines are reaching the market; and
- there is an urgent need for an EU patent and patent-litigation system.

Following publication of the Final Report, the Commission initiated a number of antitrust investigations into the practices of pharmaceutical companies, including: *Perindopril* (39.612), *Citalopram* (39.226) and

Fentanyl (39.685) (see also question 6). The Commission also commenced industry-wide monitoring of patent settlements, and to date has published seven annual reports on this issue (see also question 31). Finally, the Final Report (and subsequent enforcement cases) precipitated certain amendments to the EU Guidelines on technology transfer agreements (see questions 18 and 22).

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

Any person, including NGOs, trade associations and consumer groups, can voluntarily provide information to the Commission concerning an alleged infringement of EU competition rules.

NGOs, trade associations and consumer groups that are able to show a 'legitimate interest' are entitled to bring a formal complaint or intervene in proceedings before the Commission or the EU courts, or both. Such entities enjoy certain procedural rights. By way of example, the European Federation of Pharmaceutical Industries and Associations (EFPIA) intervened in *AstraZeneca* in its appeal before the General Court.

As mentioned in question 7, under EU law, every individual and company has a right to compensation for harm caused by an infringement of the EU antitrust rules. Therefore, as a general rule, anyone can bring an antitrust damages action in a national court of an EU member state.

Review of mergers

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

The EUMR applies to all 'concentrations' with a 'Community dimension' (see question 5), and there are no sector-specific rules or guidelines applicable to the review of mergers in the pharmaceutical industry. Prior merger decisions of the Commission show, however, that sector-specific features of the pharmaceutical industry are taken into account in merger review. For example, the Commission's review of transactions in the pharmaceutical sector have taken into account that the sector is primarily driven by innovation, and price is a less important factor, as prices are often set by national authorities taking into account patient costs. Innovation is therefore a key driver, and its dynamic nature is an important part of merger review (see, eg, *Takeda/Nycomed* (2011), *Pfizer/Hospira* (2015), and *Novartis/GSK* (*Oncology*) (2015)).

Furthermore, pharmaceutical products are life-cycle products and their specific features are necessarily taken into account in merger review when assessing the impact of a pharmaceutical merger. The competitive assessment therefore differs for each relevant market (see question 11), depending in part on the stage of the life cycle (ie, the pipeline stage, during a period of market exclusivity (owing to patent protection) and following the loss of exclusivity).

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

The Notice on the definition of the relevant market for purposes of Community competition law (1997) sets out the general principles for market definition. A 'relevant market' includes those products and services that are regarded as interchangeable from the perspective of the customer, owing to the products' characteristics, prices and intended uses.

Applying these general principles, prior Commission decisions concerning finished dose pharmaceuticals have generally used the anatomical therapeutic chemical (ATC) classification (normally ATC3) as a starting point for market analysis. (See, eg, *Sanofi/Boehringer Ingelheim* (2016); *Mylan/Meda* (2016)).

In several recent cases, however, the Commission has departed from the ATC3 class where the market investigation indicates that another market definition is more appropriate. In those cases, ATC4 class or a division by medicines based on the same active pharmaceutical ingredient (API), molecule or galenic form are used (eg, *Mylan/Meda* (2016); *Watson/Actavis* (2013); *Procter & Gamble/Teva Pharmaceuticals* (2012)). In addition, in defining markets for oncology medicines, the Commission has employed two different methods (often in combination): a categorisation by molecule or categorisation by cancer type, or both (sometimes even by the stage of cancer) (see, eg, *Pfizer/Wyeth* (2009) and *Novartis/GSK (Oncology)* (2015)). On this analysis, market data is used to identify substitution patterns (see, eg, *GSK/Stiefel* (2009)).

Within the definition of products as finished dose pharmaceuticals, the Commission typically takes into account the difference between prescription drugs and drugs available over-the-counter (OTC). These two are considered as different product markets (eg, *Takeda/Nycomed* (2011)). Although the API used may be identical, prescription and OTC medicines are subject to different legal rules and the marketing and distribution of these medicines tends to differ. With that said, in *Mylan/Meda* (2016), the Commission noted that segmentation between OTC and prescription drugs may not be appropriate where the same drugs are available both OTC and on prescription.

The geographic market for prescription finished dose pharmaceuticals, including OTC, is national in scope (eg, *Mylan/Meda* (2016); *Procter & Gamble/Teva* (2012)).

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

In the context of merger control, the Commission will assess any claimed efficiencies raised by the merging parties. Parties can present arguments that the efficiencies generated by a transaction outweigh the harm to competition that may otherwise occur.

However, claimed efficiencies must fulfil strict, cumulative conditions and it is for the merging parties to prove that they are met. First, the claimed efficiencies must be verifiable (ie, that the Commission can be reasonably certain that they will materialise and be substantial enough to counteract a merger's potential harm to consumers). Second, the efficiencies must be merger-specific (ie, they cannot be achieved by other means than by a merger). Third, it must be likely that the claimed efficiencies will redound to the benefit of consumers.

With respect to the third point, the Commission's Guidelines on the Assessment of Horizontal Mergers (Horizontal Merger Guidelines) (paragraph 81) expressly state that consumers may benefit from new or improved products or services, for instance resulting from efficiency gains in the sphere of R&D and innovation. As such, the strengthening of local or regional research and development activities can be invoked to address antitrust concerns to the extent that the aforementioned strict conditions are met.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

Given the large number of affected markets in pharmaceutical mergers (numerous product and geographic markets), the Commission applies a system of filters aimed at determining the group of markets where concerns are most likely and on which it focuses its analysis (see, eg, *Mylan/Meda* (2016); *Mylan/Abbott EPD-DM* (2015)):

- Group 1: where the parties' combined market share exceeds 35 per cent and the increment exceeds 1 per cent;
- Group 1 'plus': (i) the combined market share is below 35 per cent but only one other competitor remains on the market; or (ii) the combined market share exceeds 35 per cent and the increment is below 1 per cent but the party with the small increment is a recent entrant.
- Group 2: where the parties' combined market share exceeds 35 per cent but the increment is below 1 per cent; and
- Group 3: where the parties' combined market share is between 20 per cent and 35 per cent.

In its assessment, the Commission focuses mainly on Group 1 markets and also on instances where one party is planning to enter a market with a new product and the other party (or the parties combined) has a market share of 35 per cent or more on any possible market definition where the pipeline and existing products overlap (see, eg, *Mylan/Meda* (2016); *Procter & Gamble/Teva Pharmaceuticals (OTC II)* (2012)).

Generally, high market shares of the merging parties, in combination with much lower market shares of competitors and high barriers to entry, are likely to raise serious doubts as to the compatibility of a transaction with the common market. It is noted, however, that high market shares in themselves do not always raise competition concerns. In *Mylan/Abbot EPD-DM* (2015), for example, the Commission took a number of factors into account to show that despite combined market

shares of 50 to 60 per cent with a significant increment in some markets, the transaction did not raise competition concerns. These factors included the presence of a number of branded and generic competitors with a significant marketing and distribution footprint, the frequency of tenders for a particular product, and regulation of prices.

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

As a general matter, the Horizontal Merger Guidelines (paragraph 60) make clear that transactions involving potential competitors can be problematic where two criteria are met. First, the potential competitor must exert significant competitive pressure or be expected to do so in a relatively short period of time. Second, there must not be a sufficient number of other potential competitors that will exist after the transaction (eg, *Watson/Actavis* 2012). In the context of 'pipeline products' (ie, products that are in an advanced stage of development) the Commission has found that potential competition can also be regarded – to some extent – as actual competition (eg, *Teva/Allergan Generics* (2016); *Pfizer/Wyeth* (2009); see also the Commission's Horizontal Merger Guidelines (paragraph 38)).

Merck/Schering-Plough (2009) provides an example of the Commission's practical approach to transactions involving pipeline products. In that case, the Commission determined that markets would be analysed more closely where:

- either of the parties had an existing product and the other had a pipeline product in an advanced stage of development; or
- both parties had pipeline products relating to a specific product market in an advanced stage. Advanced stage typically means clinical trials (Phase III) (eg, *Teva/Ratiopharm* (2012); *Valeant/Bausch & Lomb* (2013)).

Markets subject to closer analysis include those in which one party is planning to enter a market with a new product within two years, and the other party has (or the parties' jointly have) a market share of 35 per cent or more in any plausible market where the pipeline and existing product overlap (see, eg, *Procter & Gamble/Teva Phamaceuticals OTC II* (2012); *Sanofi-Aventis/Genzyme* (2011)).

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

Structural remedies – in particular, divestitures – are the most commonly used type of remedy in pharmaceutical transactions, and are the Commission's overall preferred form of remedy (see eg, *Mylan/Meda* (2016); *Sanofi-Aventis/Zentiva* (2009); *Teva/Ratiopharm* (2010)). Divested assets must consist of a viable business, including all assets that contribute to the operation of the business and thus ensure its viability and competitiveness. The purpose of a divestiture is usually to create an effective new entrant or to strengthen another existing competitor to resolve competition problems raised by a transaction, in a short period of time. In some recent cases, the Commission has accepted structural remedies alongside behavioural remedies, such as the provision of technical assistance or transfer of distribution contracts where the merging parties act only as a distributor (not a manufacturer) (see, eg, *Pfizer/Wyeth* (2009), *Novartis/Alcon* (2011)).

In exceptional circumstances, the Commission may accept the granting of an IP licence in lieu of divesting a business where, for instance, it may not be possible to divest the entire business because of its nature, or where doing so would harm efficient ongoing research. Where an IP licence is accepted as a remedy, it typically must be exclusive and not encumbered by field of use or geographic restrictions. IP licences are not, however, a preferred form of remedy, mainly because licensing arrangements create more uncertainties than divestments. Thus, IP licences generally will not be accepted where the divestiture of a business is feasible (Commission Notice on Remedies, paragraph 38).

Depending on the facts of the transaction, the Commission may also accept other types of remedies, for example, the termination of exclusionary agreements or obligatory access to key technologies for competitors (see, eg, *Roche/Boehringer* (2008) and *Glaxo/Wellcome* (1995)). In *Novartis/GSK (Oncology)* (2015) approval of the transaction was conditional on, inter alia, the acquirer of the divested asset finding a suitable partner to jointly develop and commercialise the divested product.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

Where an IP right has a market presence to which market turnover can be attributed, the acquisition of intangible assets such as patents can be considered a concentration and, thus, subject to merger control.

In any event, the transfer of licences for brands, patents or copyrights, without additional assets, would typically only fulfil these criteria if the licences are exclusive at least in a certain territory and the transfer of such licences transfers the turnover-generating activity.

Anticompetitive agreements

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

Agreements and practices are governed by the provisions of article 101 TFEU. There are three elements to a breach of article 101(1):

- there must be an agreement, decision or concerted practice between two or more independent companies;
  - that may affect trade between EU member states to an appreciable extent; and
  - that has as its object or effect the restriction, prevention or distortion of competition within the EU (eg, by fixing purchase or selling prices or other trading conditions; limiting or controlling production, markets, technical development or investment; or sharing markets or sources of supply).

However, this is subject to the exemption under article 101(3) TFEU, which is available to agreements that:

- bring efficiency benefits, or promote technical or economic progress;
- allow consumers a fair share of the resulting benefits;
- do not restrict competition more than is indispensable to the achievement of the pro-competitive objectives; and
- do not allow for competition to be eliminated.

Companies are obliged to assess for themselves whether their practices comply with article 101 TFEU.

There are also several block exemption regulations, pursuant to which agreements fulfilling certain defined criteria will be deemed to automatically qualify for an exemption under article 101(3) TFEU. The following block exemptions are of specific relevance to the pharmaceutical sector: Commission Regulation (EU) 316/2014, which concerns technology transfer agreements (TTBER); Commission Regulation (EU) 1217/2010 concerning research and development agreements; and Commission Regulation (EU) 330/2010 concerning distribution agreements.

18 To what extent are technology licensing agreements considered anticompetitive?

The legal framework for the assessment of technology licensing agreements is contained in the TTBER and the accompanying Guidelines on technology transfer agreements (Technology Transfer Guidelines) (see question 17.) The TTBER provides that certain technology licensing agreements are exempt under article 101(3) TFEU where certain conditions are met, namely:

- the market share of the contracting parties is less than 20 per cent combined, where the parties are actual or potential competitors, or less than 30 per cent each, where the contracting parties are non-competing firms; and
- the agreement contains no hard-core restrictions that would prevent the application of the block exemption.

Hard-core restrictions can include, inter alia, price fixing or resale price maintenance, limits on production, exclusive allocation of geographic markets or customers (there are some exceptions), restricting a licensee's ability to exploit its own technology or, in some cases, restricting passive (unsolicited) sales (there are some exceptions). Technology licensing agreements that contain hard-core restrictions do not qualify for a block exemption under the TTBER and are unlikely to qualify for an individual exemption under article 101(3) TFEU.

If an agreement falls outside of the scope of the TTBER, it must be assessed under the general provisions of article 101 TFEU.

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

A co-marketing agreement refers to the joint selling and marketing of a single product under different brands. A co-promotion agreement, in contrast, involves combining commercialisation efforts (eg, sales (pricing), promotion and distribution) for a pharmaceutical product under a single trademark.

Both are common forms of commercialisation agreements in the pharmaceutical industry, and they are subject to article 101 TFEU, concerning anticompetitive agreements (see question 20). The Commission mentioned both co-marketing and co-promotion agreement in its Final Report following its sector inquiry (paragraph 1288), but did not provide specific guidance on the antitrust treatment of these agreements.

In practice, co-marketing and co-promotion agreements may raise antitrust concerns if they result in price fixing, limiting output, market sharing or the exchange of sensitive information among competitors.

This is less likely to occur in the context of co-marketing agreements, provided that each company bears individual responsibility for setting prices and distribution strategies, that the parties do not share revenues and otherwise ensure that sensitive information is not shared between them. There have been no cases to date in which pharmaceutical companies have faced penalties for entering into a co-marketing agreement.

Co-promotion agreements bring together competitors for the purposes of jointly promoting a pharmaceutical product and involve revenue sharing. As horizontal agreements, co-promotion agreements have resulted in greater scrutiny by the Commission, which has led to enforcement. For example, in *Fentanyl* (2013), the Commission fined Johnson & Johnson €10,798,000 and Novartis €5,493,000 for their participation in a co-promotion agreement for Fentanyl on the Dutch market. The Commission concluded that this co-promotion agreement infringed article 101 TFEU because it provided strong incentives for Novartis' Dutch subsidiary to delay entering the Dutch market with a generic fentanyl product, which in turn led to artificially high prices on the Dutch market. This decision was not appealed.

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

Article 101 TFEU applies to all forms of agreement with actual or potential competitors (see questions 17–19). Agreements with actual or potential competitors are likely to raise competition problems when they involve hard-core restraints, such as price fixing, restricting output, allocating markets or customers, or involve the sharing of commercially sensitive information (eg, on pricing). Agreements containing these types of provisions are very likely to infringe article 101 TFEU by 'object', meaning that it is not necessary to show anticompetitive effects resulting from the agreement.

Other agreements (eg, licence agreements, R&D agreements, production joint ventures) that do not contain hard-core restraints are subject to an effects-based analysis.

In all cases, it is important that companies ensure that their commercially sensitive information is not shared among actual or potential competitors. This may mean that safeguards need to be put in place to limit the flow of commercially sensitive information. For example, the Commission encourages the use of independent experts or licensing bodies when calculating royalties, so that output and sales data remain confidential.

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

As a general matter, vertical agreements – that is agreements between companies active at different levels of trade – are subject to article 101 TFEU. Vertical agreements may also benefit from a block exemption that concerns vertical distribution agreements (Regulation 330/2010; see question 17), provided that certain criteria are met and that the agreement does not contain hard-core restrictions. In vertical agreements, restricting a distributor's ability to make passive (ie, unsolicited) sales is considered to be hard core.

In the pharmaceutical sector, in practice, vertical agreements that limit or restrict parallel trade (such as those containing dual pricing mechanisms) have raised antitrust concerns (see question 3). The CJEU held in *GSK* (Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P) that any agreement limiting parallel trade is a 'by object' violation of article 101(1) TFEU and does not benefit from an individual exemption under article 101(3) TFEU.

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

In 2014, the Commission issued updated Technology Transfer Guidelines. The Technology Transfer Guidelines, and recent enforcement cases, provide that certain patent settlement agreements are likely to create antitrust concerns where they have the effect of delaying or limiting entry of generic medicines onto a market. A patent settlement agreement is likely to create antitrust concerns, and expose the parties to antitrust liability, in the following circumstances:

- the agreement has been entered into between actual or potential competitors. In this respect, the Commission applies a wide definition of 'potential competition'; merely being perceived to be a potential competitor by incumbents may be sufficient (see, eg, *Lundbeck* (2013)). The fact that a new (generic) entrant's launch could infringe the originating manufacturer's IP rights does not affect its status as a potential competitor as long as the entrant believes at the time that it could successfully defend a patent infringement claim;
- the entry of a competing generic product has been delayed as a result of the settlement and, in return for the delay in entry, the generic manufacturer obtains some form of consideration from the incumbent originator (value transfer). Value transfers can take many forms, for example, direct monetary transfer, compensation for the generic's legal costs, purchase of an asset, conclusion of a distribution agreement (ie, a side deal) or granting a patent licence to the generic company; or
- the inclusion of a non-challenge clause in a reverse payment patent settlement agreement may be a contributing factor to the finding that the agreement as a whole infringes article 101(1) TFEU. As noted in the Technology Transfer Guidelines, it is in the public interest that invalid IP rights be removed.

See questions 6 and 8.

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

Article 101(1) TFEU prohibits the anticompetitive exchange of information across all industrial sectors, including the pharmaceutical industry. As such, the exchange of commercially sensitive information between competing pharmaceutical companies (in whatever form and regardless of setting) will likely infringe article 101(1) TFEU and not be exempted under article 101(3) TFEU.

It could be argued that the requirements on pharmaceutical companies to make disclosure of arrangements with HCOs and HCPs (see, eg, the EFPIA Disclosure Code) could increase the risk of competitors aligning their conduct. As such, there is potentially a greater risk of anticompetitive exchanges of information taking place in the pharmaceutical sector. Consequently, compliance efforts are crucial to ensure that mandated information exchanges do not infringe article 101 TFEU.

Anticompetitive unilateral conduct

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

Article 102 TFEU provides that a company in a dominant position can abuse that position, in particular by:

- directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- limiting production, markets or technical development to the prejudice of consumers;
- applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; or
- making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations that, by their nature or

according to commercial usage, have no connection with the subject of such contracts.

It is not illegal for a company to hold a dominant position. Article 102 TFEU provides that when companies hold a dominant position, they have a special responsibility not to engage in certain exclusionary or exploitative conduct.

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

According to case law (*United Brands* (Case 27/76)), a company enjoys a dominant position when its economic strength enables it to behave to an appreciable extent independently of its competitors and customers, and ultimately of consumers, therefore allowing the company to prevent or hinder competition.

The Commission outlined its general approach to dominance in its Guidance on the Commission's Enforcement Priorities in Applying Article [102 TFEU] (Article 102 Guidance). According to the case law and this Guidance, a finding of dominance will be unlikely with a market share of less than 40 per cent in the relevant market. In markets characterised by innovation, the trend and development of market shares will be taken into account in the analysis of dominance, such that high market shares are a less reliable indicator of dominance in these markets. Other relevant factors in the assessment of dominance are barriers to entry to and expansion in the market, including legal barriers such as intellectual property rights.

As for collective dominance, a dominant position may be held jointly (or collectively) where two or more independent undertakings are linked in such a way that they implicitly adopt a common policy on the market (Case C-396/96 P, *Compagnie Maritime Belge v Commission*). In Case C-342/09 *Airtours v Commission*, the CJEU outlined further criteria of collective dominance. Under *Airtours*, the market must be sufficiently transparent that the jointly dominant firms must be able to monitor one another; the jointly dominant firms must have no incentive to depart from the common policy; and competitors and customers must not be foreseeably likely to jeopardise the common policy.

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

Merely holding a patent does not confer dominance. As discussed in question 25, a determination of whether a firm is dominant involves an assessment of the overall competitive structure and features of the market. Thus, holding a patent would confer dominance if, in the market context, it allowed a firm to behave to an appreciable extent independently of competitors or customers.

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

An application for a grant of a patent can expose the patent owner to antitrust liability where the dominant firm misuses the patent system. For example in *AstraZeneca* (2005), the Commission found that AstraZeneca had abused its dominant position for medicines based on omeprazole when it sought a Supplementary Protection Certificate for its branded Losec medicine based on misleading representations to national patent officers. The General Court (2010) and CJEU (2012) both confirmed that the submission of misleading information for the purpose of obtaining an exclusive right to which a dominant firm is otherwise not entitled can amount to an abuse of a dominant position.

Likewise, patent enforcement can lead to antitrust liability where it is used to unjustifiably exclude competitors or reduce competition. The Commission's Final Report on the Pharmaceutical Sector noted unjustified patent enforcement as a strategy used to deter generic entry, which can lead to antitrust liability. To take one example, according to the General Court in *ITT Promedia NV* (Case T-111/96), a company may be found to abuse a dominant position when it brings litigation that cannot be considered to establish its rights and is only designed to harass the opposing party, or is part of a plan to eliminate competition.

In the Commission's 2014 decision in *Servier*, which is currently being appealed to the General Court, the Commission also found that the acquisition of technology may infringe article 102 TFEU, where it forms part of a dominant firm's broader strategy to eliminate competitive threats. It should be noted, however, that the Commission cautioned that the acquisition of technology by dominant undertakings is not generally prohibited and that its decision in *Servier* was limited to the specific facts of that case. (See question 28).

Update and trends

Following the decision of the General Court in *Lundbeck* (2016), appeals of the Commission's decisions concerning patent settlement agreements will continue to be closely watched. The Commission welcomed the General Court's ruling in *Lundbeck*, which upheld the Commission's 2013 decision and concluded that reverse patent settlement agreements can constitute a restriction of competition 'by object' under article 101 TFEU. Lundbeck has appealed this case to the Court of Justice of the EU. Several other cases challenging Commission decisions regarding patent settlement cases are still pending at the General Court.

In terms of mergers, recent cases show the Commission's increased focus on innovation, in particular assessing competition between merging parties' Phase III pipeline products and products on the market, as well as 'pipeline to pipeline' competition. (see, eg, *Mylan/Meda* (2016); *Novartis/GSK (Oncology)* (2015)). This can be expected to continue into the future. The *Dow/DuPont* case currently under review by the Commission, although not in the pharmaceutical sphere, seems to be a further illustration of the Commission's focus on preserving innovation as a key element of competition.

Finally, the Commission appears to be more closely scrutinising exploitative conduct by dominant firms, in particular excessive pricing and the imposition of unfair terms by dominant pharmaceutical companies. In a November 2016 speech, European Commissioner for Competition Margrethe Vestager noted that it may be appropriate for competition regulators to intervene in response to excessive prices in the pharmaceutical industry and noting recent actions taken by the British and Italian NCAs in this area. This is an area to closely watch in the coming year.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

Ordinary course life-cycle management strategies alone are generally unlikely to expose a patent owner to antitrust liability, unless the patent owner holds a dominant position and the life-cycle management strategy excludes actual or potential competition.

The Commission's Pharmaceutical Sector Inquiry noted that originator companies use a variety of life-cycle strategies, including filing a number of patent applications for the same medicine, or filing patent applications for second-generation products. However, this alone is unlikely to be problematic unless, for example, the regulatory approvals are obtained on the basis of misleading information (*AstraZeneca* (2005, upheld in 2010 and 2012)) or otherwise form part of a strategy to exclude generic entry (see *Servier* 2014). As noted above, Servier also acquired advanced non-infringing technology and concluded reverse patent settlement agreements with potential generic entrants, which was found to infringe articles 101 and 102 TFEU). (See also Question 27). The *Servier* case has been appealed to the General Court.

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

As a general rule, a patent holder may 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.

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

In any case involving an infringement of EU antitrust rules, in particular article 102 TFEU, the specific features of an industry have to be taken into account. In these cases, it is for the company to advance an objective justification for its conduct. The pharmaceutical sector has several unique features, given that national laws typically require wholesalers and distributors to ensure an adequate supply of medicines (see also question 3). At the same time, national laws also

regulate the prices and medicines that are available that are then typically prescribed by doctors – not chosen directly by consumers.

The Commission's and EU courts' approach to this issue can be illustrated by two cases involving GSK in the Greek market, *Syfait* (C-53/03, (2005)) and *Lelos* (C-468-478/06, (2009)). These cases involved allegations that GSK refused to fulfil orders of Greek wholesalers, thereby restricting parallel exports and amounting to an abuse of GSK's dominant position. The CJEU ultimately ruled that a dominant firm abuses its dominant position when it refuses to fulfil 'ordinary' orders from wholesalers. Yet, the CJEU acknowledged that a supplier must be able to protect its commercial interests if confronted with unusually large orders. It is therefore clear that pharmaceutical companies are able to provide an objective justification for conduct that would otherwise infringe the antitrust rules, but that these claimed justifications will be closely scrutinised.

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

At the EU level, since the EU Sector Inquiry, the Commission has initiated several investigations into the pharmaceutical sector. The Commission's enforcement focus has been on anticompetitive settlement agreements ('pay-for-delay' agreements) (see questions 6, 8, 19 and 28). Many of these Commission decisions have been appealed (*Sun Pharmaceutical Industries and Ranbaxy* (UK) (T-460/13); *Generics* (UK) (T-469/13); *Merck* (T-470/13); *Xellia Pharmaceuticals and Alpharma* (T-471/13); *Arrow Group and Arrow Generics* (T-467/13); *Unichem Laboratories* (T-705/14); *Mylan Laboratories and Mylan* (T-682/14); *Teva UK and Others* (T-679/14); *Krka* (T-684/14); *Lupin* (T-680/14); *Servier and Others* (T691/14); *Biogaran* (T-677/14) and *Niche Generics* (T-701/14)). The *Lundbeck* (2013) decision was also appealed to the General Court, which upheld the Commission's decision. This case was closely watched as it represented the first of the Commission's recent enforcement efforts with respect to patent settlement agreements.

In addition, since the EU Sector Inquiry, the Commission has been monitoring patent settlements between originator and generic companies and has published annual reports. In December 2016, the Commission published its seventh and latest report on the monitoring of patent settlements. The seventh report concluded that the number of settlements that might attract competition law scrutiny has stabilised at a low level. Indeed, according to the report, 90 per cent of the settlements reached fall into categories that prima facie do not warrant competition law scrutiny. According to the report, therefore, 'companies, in most cases, are able to solve their disputes in a manner that is typically considered unproblematic from a competition law perspective'.

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The national applicable legislation for pharmaceuticals includes the Medicines Act (395/1987) and the Medicines Decree (693/1987). The national legislation is also supplemented by the regulations and guidance issued by the Finnish Medicines Agency, Fimea. Pharma Industry Finland (PIF), an organisation of the innovative pharmaceutical industry, has also issued its Code of Ethics, the PIF Code, containing detailed provisions regarding marketing of medicines, which are binding for members of the organisation. Overall, marketing of pharmaceuticals to consumers, if permitted, must also meet the requirements of the Finnish Consumer Protection Act (38/1978) and the Regulation on unfair practices in marketing and customer relations (601/2008). The main bodies responsible for enforcing the legislation are Fimea, the Pharmaceuticals Pricing Board, the National Supervisory Authority for Welfare and Health, and the National Institute for Health and Welfare. These are all subordinated to the Ministry of Social Affairs and Health. In addition, the Supervisory Commission for the Marketing of Medicinal Products enforces the above-mentioned PIF Code.

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

The Medicines Act includes detailed provisions regarding the distribution of pharmaceuticals. All distribution activities of pharmaceutical products are subject to a wholesale licence in Finland granted by Fimea. In order to be eligible for a licence, the applicant must, for example, be situated in Finland and have proper facilities and equipment for the storage of medicinal products and for ensuring the operations and the personnel required for the operations. Pharmaceuticals may be sold or otherwise supplied by the wholesaler to a medicinal product manufacturer, another medicinal product wholesaler, a pharmacy, subsidiary pharmacy, the Military Pharmacy, a hospital pharmacy or dispensary or to a veterinary surgeon for the purposes of veterinary medication. Fimea has also issued a regulation (5/2013) on good distribution practices. Under the Medicines Act, the operation of a pharmacy business requires a pharmacy licence issued by Fimea. The granting of a licence is subject to, inter alia, a means test based on the population of the area in which the pharmacy is located.

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

The mandatory prerequisites for obtaining and maintaining relevant licences under the Medicines Act, as well as compliance with Fimea's regulations and instructions, set out the framework for distributing and marketing pharmaceutical products in Finland. Further, the national rules on pricing and reimbursement of pharmaceutical products limit possibilities of price adjustments and discounts. For example, under the Medicines Act, the holder of the relevant marketing authorisation is responsible for notifying prices to public price lists, and no individual discounts from distributors to pharmacies are allowed; the price of a pharmaceutical product must be the same for every pharmacy in Finland and in accordance with the notified price.

Competition legislation and regulation

4 Which legislation sets out competition law?

Competition legislation in Finland is, in essence, set out in the Competition Act (948/2011).

The Ministry of Employment and the Economy has further issued regulations concerning the application of the merger control rules included in the Competition Act. The Finnish Competition and Consumer Authority (FCCA) has issued guidelines on topics such as merger control, possibilities to seek immunity or reductions in fines and the prioritisation of the FCCA's tasks.

The Competition Act is a general law that applies to all sectors of the economy. Only limited exceptions apply, which are within the fields of labour agreements and agriculture.

In addition to the national Competition Act, articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU) apply if a competition restraint may affect trade between member states.

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

There are no specific authorities or courts dealing with competition law infringements in the pharmaceutical sector.

The FCCA is the competent authority to investigate and decide on all mergers and acquisitions that exceed the turnover thresholds as set out in the Competition Act, regardless of the industry in question. However, the FCCA cannot prohibit a notified merger or acquisition, but has sole jurisdiction to propose the prohibition of such a transaction to the Market Court. Similarly, the FCCA investigates alleged infringements of competition law and can, for example, order the parties to cease and desist from continuing an infringement, but decisions on fines are issued by the Market Court as the first instance.

The Market Court's decisions are appealable to the Supreme Administrative Court.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

The FCCA may impose various remedies for anticompetitive conduct or agreements. The FCCA has sole jurisdiction to propose fines (an administrative penalty payment) to be imposed by the Market Court on undertakings or associations of undertakings party to an infringement. The amount of the fine shall not exceed 10 per cent of the turnover of the party to the infringement.

The FCCA may also issue a decision ordering the parties to cease and desist an infringement or order a company to deliver its products to another undertaking under the same conditions that it delivers to other companies. The FCCA may also impose commitments by the parties to an alleged infringement as binding and, on that basis, close the case file without further measures.

The FCCA has investigated several suspected infringements in the pharmaceutical sector, but these investigations have ended with the FCCA closing the case without further measures. In cases relating to

other industries, the FCCA has proposed fines of up to €70 million to be imposed on an individual company for an infringement relating to the abuse of a dominant position and up to €68 million concerning horizontal cooperation, both of which have been accepted by the Supreme Administrative Court.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Private parties may submit a complaint to the FCCA in the event they suspect a competition law infringement, and the FCCA may use such a complaint as basis for launching an investigation into the matter. However, under the Competition Act, the FCCA is entitled to prioritise the cases it investigates, and can close a case without further measures if it is, for instance, unlikely that the conduct in question would have a significant impact on the conditions of sound and effective competition.

Private parties can also claim for damages in the Finnish general civil courts based on a competition law infringement. The Act on Antitrust Damages Actions (1077/2016) includes specific provisions under which damages resulting from an infringement of competition law can be claimed. The Act implements the EU Directive on Antitrust Damages Actions, and it entered into force on 26 December 2016.

To our knowledge, damages have not been claimed by private persons based on an infringement of competition law in the pharmaceutical sector in Finland. However, recently it has become very typical for damages to be claimed by injured parties in cases where the FCCA (and subsequently the courts) have found a company to have been party to an infringement of competition law. The total value of competition law-related damages claims currently pending in the Finnish civil courts is in the range of several hundred million euros.

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

The FCCA may conduct sector-wide inquiries and publish reports and studies related to the market conditions in specific sectors.

In 2012, the FCCA published a comprehensive study on competition in the Finnish pharmaceutical industry titled 'From the provision of pharmaceutical products to pharmaceutical markets – Value chain and regulation'. In the study, the FCCA assessed the need to reform the legislation concerning the pharmaceutical industry and the wholesale of medicines. On the basis of this analysis, the FCCA proposed several amendments to the legislation that were aimed at improving the efficiency and productivity of the provision of pharmaceutical products in Finland. However, the proposed amendments were mainly directed at the Finnish pharmacy system and the retail sector of pharmaceutical products. The FCCA recommended, for example, that the means testing in establishing new pharmacies, as well as other restrictions regarding the amount of pharmacies, should be abolished.

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

Non-governmental groups do not play any particular role in the application of competition rules to the pharmaceutical sector, and there are no particular statues in law concerning such interaction between the FCCA and non-governmental groups. The FCCA may consult such non-governmental groups when, for example, analysing market conditions and in the course of sector-wide inquiries, and such groups can, similarly to all other parties, lodge complaints to the FCCA concerning suspected infringements of competition. Non-governmental groups do not have any particular standing in private antitrust litigation.

To the extent a non-governmental group can be considered to be an undertaking or association of undertakings, the conduct of such a group may also infringe competition rules, and the non-governmental group can be targeted by an investigation of the FCCA. The FCCA has investigated practices of trade associations in various fields of industry from time to time.

Review of mergers

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

In recent years, no pharmaceutical industry mergers or acquisitions have been notified to the FCCA.

Since the introduction of merger control in Finland in 1998, the following cases concerning the pharmaceutical industry have been notified to the FCCA:

- *Idec Pharmaceuticals Corporation/Biogen Inc*, Decision No. 555/81/2003, 4 August 2003;
- *Nycomed Pharma AS/Oy Leiras Finland Ab*, Decision No. 1106/81/2002, 23 December 2002;
- *Orion-yhtymä Oyj/Kronans Droghandel Ab*, Decision No. 7/81/2002, 22 May 2002;
- *Leiras Oy – Produits Chimiques Auxiliaires de Synthèse SA/Leiras Fine Chemicals Oy*, Decision No. 650/81/2001, 1 August 2001; and
- *Nordic Capital III Limited/Nycomed Amersham Norge AS*, Decision No. 472/81/99, 24 June 1999.

The merger control decisions adopted by the FCCA in these cases are rather straightforward and do not provide extensive discussion on the FCCA's analyses in the matters. It is, however, noteworthy that the FCCA has drawn attention to certain sector-specific issues, such as the potential impact of the Finnish pharmaceutical single-channel wholesale distribution system in the competitive assessment of a merger.

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

In the cases notified to the FCCA, the product and geographic markets were defined by the notifying party on the basis of the definitions that follow the European Commission's practice. In the most recent decision, that is *Idec Pharmaceuticals Corporation/Biogen Inc* (see question 10), the notifying party referred to the Commission's decisions where it has applied the anatomical therapeutic chemical (ATC) classification as a basis for product market definition. The ATC classification consists of four different levels, and in this case, the analysis was conducted on the third level, which allows medicines to be grouped according to their therapeutic indications. As regards the geographic dimension of the market, the notifying party submitted that it was national because of the differences in the legislation between the countries at the time of notification (ie, 2003).

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

Under the Competition Act, the parties may invoke the 'efficiency defence', under which agreements otherwise restrictive of competition are considered to be in accordance with the Finnish Competition Act. For details of the efficiency defence criteria, see question 17.

In the assessment of the efficiency defence criteria, the strengthening of local or regional R&D activities does not play any particular role. The promotion of technical or economic progress is taken into account irrespective of the territory where it is generated (ie, the strengthening of local or regional R&D does not have any particular preference over a similar increase in R&D efforts on a national basis or outside Finland).

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

The FCCA may propose to the Market Court the prohibition of a transaction that may significantly impede effective competition in Finland or a substantial part of it, in particular if the transaction creates or reinforces a dominant position. The FCCA, therefore, assesses notified mergers and acquisitions under a similar framework as the European Commission. In cases where the parties are currently active in the same product and geographical market, the FCCA will investigate whether the transaction may lead to the combined entity (or one or more competitors) having the ability and incentive to raise prices (eg, directly or by foreclosing competitors from the market).

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

A merger of pharmaceutical companies that both have similar products under a late stage of development could potentially lead to competition concerns if the companies could successfully bring the products to market if the transaction does not take place. The FCCA could argue that absent the transaction, the two companies would launch products in competition with each other, whereas the combined entity would not create such competition on the market. For example, in *Idec Pharmaceuticals Corporation/Biogen Inc* the FCCA drew attention to the fact that the products under development (in Phases II and III) by the target would not be competing products to those supplied by the acquirer.

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

The FCCA (and ultimately the courts) may accept, as condition for clearance to a notified merger or acquisition, both structural and behavioural remedies. Generally divestiture remedies may be more effective in resolving competition concerns. Remedies could also include assigning or licensing acquired patents to third parties.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

The FCCA has not considered an acquisition comprising solely a patent or a patent licence under merger control rules to date. Nor does the FCCA provide detailed guidance on this issue in its merger control guidelines. However, reference can be made to the European Commission's consolidated jurisdictional notice, which considers that an acquisition confined solely to patents can be considered a notifiable transaction if the assets transferred constitute a business with a market turnover. The transfer of a patent licence, without additional assets, however, can only fulfil this criterion if the licence is exclusive at least in a certain territory and the transfer of the licence will transfer the turnover-generating activity.

Anticompetitive agreements

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

Under the Competition Act, the general framework in assessing whether an agreement or practice can be considered anticompetitive comprises:

- a prohibition on agreements by undertakings, decisions by associations of undertakings or concerted practices that have as their object or effect the significant prevention, restriction or distortion of competition (section 5 of the Competition Act). This statute is similar to article 101(1) TFEU except that for the prohibition to apply, the restriction need not affect trade between member states; and
- an exemption to the prohibition set out above (section 6 of the Competition Act). This 'efficiency defence' exemption is similar to that of article 101(3) TFEU. For the exception to apply, the restriction of competition must fulfil the following four cumulative criteria:
  - the restriction contributes to improving the production or distribution of goods or promotes technical or economic progress;
  - it allows consumers a fair share of the resulting benefit;
  - it does not impose restrictions on the parties that are unnecessary to achieve the benefits; and
  - it does not afford the undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

18 To what extent are technology licensing agreements considered anticompetitive?

The Finnish competition legislation does not provide particular guidance concerning the assessment of technology licensing agreements. The guidance provided in the European Commission's Technology Transfer Block Exemption Regulation (316/2014) and related guidelines provide further insight into the assessment of technology licensing agreements.

Update and trends

There have been some changes to the pricing and reimbursement system in Finland from the beginning of 2017 due to political decisions on public cost savings in the pharmaceutical sector. The changes aim at the broader use of biosimilars, and include parallel trade products to the generic substitution system. Some of the changes, for example, the limited possibility of granting conditional reimbursement status to a new pharmaceutical treatment in connection with a risk-sharing agreement between the Pharmaceutical Pricing Board of the Ministry of Health and Social Affairs and the marketing authorisation holder, are only temporary at this stage. Since the overall purpose of the changes is to enhance competition and to diminish costs, the new regulations are not very likely to give rise to major antitrust concerns.

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

Co-promotion and co-marketing agreements have not yet been investigated in detail by the FCCA. However, the same principles (which the European Commission recently followed in the assessment of such agreements) could be expected to be the starting point of the FCCA's analysis.

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

As the prohibition of agreements restrictive of competition in the Competition Act is a general provision and can apply to all kinds of conduct that have as their object or effect the restriction of competition; in particular, competitors should always carefully assess any cooperation agreements that include restrictive terms or could otherwise be seen to have a restrictive purpose or effect.

Depending on the arrangement, confidentiality provisions may be sufficient to mitigate competition concerns (eg, appropriately limiting the amount of information exchanged between two pharmaceutical companies that engage in joint R&D). However, in many kinds of cooperation between competitors, confidentiality agreements alone may not be sufficient to resolve competition concerns.

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

Similar to the European Commission's Vertical Block Exemption Regulation (330/2010), the main aspects of vertical agreements that raise concern are provisions relating to the resale pricing of products by a distributor and territorial or customer restrictions imposed on a distributor. However, a distinctive feature of the Finnish pharmaceutical sector is the extensive regulation concerning the pricing of pharmaceutical products. An assessment of, for example, restrictions in resale pricing by a distributor, should take into consideration the complex regulatory framework, which affects the possibilities of pricing products at the various levels of distribution.

As another distinct feature, currently only two major wholesalers exist in Finland, and manufacturers typically distribute their products only through one of them (the 'single-channel distribution system'). The FCCA has investigated the single-channel distribution system on several occasions and has closed each of its reviews without further measures, most recently in 2012.

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

The FCCA has not taken any decisions concerning patent settlement agreements. However, the guidance provided in the European Commission's technology transfer guidelines and the cases investigated by the European Commission and the General Court's judgment in *Lundbeck* (T-472/13) would likely be a starting point in the FCCA's assessment of the competitive effects of a patent settlement agreement entered into by companies in the pharmaceutical sector.

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

The fulfilment of transparency requirements set forth in mandatory legislation is not likely to give direct rise to anticompetitive information exchange caught by the Competition Act. Nor should anticompetitive information exchange be considered more likely in the pharmaceutical sector in Finland, as the general guidance provided by the EU Commission regarding information exchange is well known by the Finnish pharmaceutical companies, and they strictly follow applicable competition rules.

Anticompetitive unilateral conduct

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

Under section 7 of the Competition Act, the following conduct in particular, may be considered anticompetitive by a dominant company:

- directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- limiting production, markets or technical development to the prejudice of consumers;
- applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; and
- making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations that, by their nature or according to commercial use, have no connection with the subject of such contracts.

The list of conduct above is not exhaustive, and, in principle, all kinds of conduct with an exclusionary, exploitative or distortionary effect on the market could fall within the prohibition on the abuse of a dominant position.

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

The Finnish competition legislation does not include any particular thresholds for the assessment of dominance in the pharmaceutical sector. However, in general a market share of 40 per cent in a properly defined relevant market, combined with other factors, may lead to a presumption of dominance, and a market share of 50 per cent may, as such, lead to the presumption of dominance.

To date, the FCCA has not found any company in the pharmaceutical industry to hold a dominant market position.

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

It should not be sufficient to find dominance solely on the basis of ownership of an intellectual property right, such as a patent. However, depending on market circumstances, the ownership of a patent may be a relevant factor in establishing dominance.

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

The FCCA has not issued any decisions where it would have considered that an application for the grant of a patent would have been an antitrust violation or a part of such a violation. However, the EU Court's judgment in *AstraZeneca v Commission* (C-457/10 P) would likely be seen as a relevant precedent in assessing conduct relating to applications for intellectual property protection.

The FCCA has not issued any decision where it would have considered the enforcement of a patent to constitute an antitrust violation or a part of such violation. The FCCA would likely consider the EU Court's precedent and the European Commission's practice as relevant, should a case relating to the enforcement of patents come under investigation.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

The FCCA has not issued any decisions concerning life-cycle management strategies of pharmaceutical companies. Nonetheless, pharmaceutical companies should be careful in assessing whether life-cycle management strategies include any anticompetitive means to exclude competitors from the market. While pharmaceutical companies may legitimately seek intellectual property protection for their innovations to the fullest extent permitted by law, measures to artificially extend protection beyond the purpose of the intellectual property protection might, in particular circumstances, expose the patent owner to liability for an antitrust violation.

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

Authorised generics, as such, have not been seen to raise issues under Finnish competition law. However, pharmaceutical companies must always assess whether their conduct could constitute an abuse of a dominant position or whether an agreement concerning generics could have as its object or effect the restriction of competition.

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

The pharmaceutical sector does not enjoy any particular exemption from the application of Finnish competition law. However, the Finnish legislation concerning the pharmaceutical sector should be taken into consideration when assessing whether a particular type of conduct is contrary to competition law. This may be relevant, in particular concerning the distribution of pharmaceutical products in Finland in view of the existing legislation on, for example, pricing and availability.

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

The FCCA has not published information of any inquiries relating to life cycle management or settlement agreements since the EU Sector Inquiry.

France

Christophe Hénin and Julie Vasseur
Intuity

Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The French Public Health Code (PHC) regulates the marketing authorisation (MA) of reference medicinal products for human use (articles L 5121-8 and R 5121-21 and following) and generic products (articles L 5121-10 and R 5121-5 and following).

Applications for MAs are submitted to the French National Agency for the Safety of Medicines and Health Products (ANSM). A simplified procedure exists for generics that have to prove the bioequivalence of their product with reference to the original medicine.

Any company marketing medicinal products without prior authorisation incurs two years' imprisonment and a fine of €375,000 (article L 5421-2 of the PHC). The ANSM is competent to control the validity of the MAs but not to impose these sanctions, which may solely be decided by the criminal court after instruction by the public prosecutor.

After having obtained an MA for its medicine, a pharmaceutical firm may decide on which market to place its product. A key distinction must be made between the hospital market for inpatients and the pharmacy market for outpatients:

- for the hospital market, pricing is free and prices are set through bids (except for medicines that can be purchased by outpatients and for most innovative medicines for which prices are set according to a procedure similar to the one applying to pharmacy reimbursable medicines as described below); and
- for the pharmacy market, the firm can choose to enter the non-reimbursable market or the reimbursable market:
  - if it chooses the non-reimbursable market, pricing is totally free; or
  - if it chooses the reimbursable market, the price is then regulated and set by convention between the Economic Committee for Health Care Products (CEPS) and the firm.

The price determination process takes into account various criteria set out in article L 162-16-4 of the French Social Security Code, including the improvement of clinical benefit evaluated by the Transparency Commission of the French National Authority for Health, the prices of other medicinal products with a similar therapeutic design, the expected or recorded sales volume and the actual and foreseeable use of the medicinal product.

For generics, the price set out by the CEPS is 60 per cent lower than a reference medicinal product.

Major changes have recently been implemented in French pharmaceutical sector regulation in the aftermath of the Mediator affair. On 29 December 2011, parliament adopted a major reform, Law No. 2011-2012, which concerns some key aspects with respect to transparency of related interests, governance of health products, medicinal products and medical devices. Some of its provisions have been adjusted by Law No. 2012-1404 on Social Security System Financing dated 17 December 2012 or clarified by implementation decrees. More specifically, the transparency of related interests has been organised by Decree No. 2013-414 of 21 May 2013, which clarifies which kind of payment or transfer of value must be reported and sets out a threshold of €10, above which advantages provided by pharmaceutical firms to healthcare professionals must be reported.

Only administrative courts have jurisdiction to hear on actions against marketing authorisations, decisions fixing the price or decisions regarding the reimbursement of a product.

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

There is specific legislation on the distribution of pharmaceutical products, which is mainly developed in the PHC. The most important points are as follows.

First of all, as regards distribution to patients, pharmacists keep the monopoly on the sale of most medicines and in vitro medical devices (article L 4211-1 of the PHC) through brick or click (through both physical shops and online). However, on the internet pharmacies are only authorised to sell non-prescription medicines (order dated 20 June 2013). This being said, the pharmacists' monopoly is nowadays subject to various criticisms, ranging from the European Commission to supermarket chain holders. In order to comply with European case law in this matter, France decided to exclude contact lenses and accessories from the monopoly, as well as pregnancy tests (Law dated 17 March 2014).

Upstream, the whole supply chain is strongly regulated, thus limiting competition between the various actors.

Prices are only set out freely for the supply to hospitals (see question 1), whereas for the 'in town' circuit, the retail price (including taxes) is set out by the CEPS. The maximum margins that can be applied at each step of the supply chain (wholesalers and pharmacists) are set out by law (order dated 4 August 1987, modified since). The theoretical 'manufacturer price, excluding taxes' (the price to be applied by the pharmaceutical company) is calculated as a result of the application of these maximum margins to the retail price.

This mechanism results in a significant rigidity and considerably hinders horizontal competition, all the more so as discounts to pharmacists are strictly capped. Therefore, pharmaceutical companies directly selling to pharmacists or wholesalers supplying pharmacists cannot offer discounts exceeding 2.5 per cent of the manufacturer's price on originator medicines and 40 per cent on generics (see question 3), provided such products are reimbursed by social security funds.

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

Several aspects of the above legislation are relevant to the application of competition law to the pharmaceutical sector.

As prices are set out by public bodies, competition between pharmaceutical firms is limited in this field.

Article R 5124-59 of the PHC, which was modified by Decree No. 2012-1096 of 28 September 2012, imposes public service obligations on wholesalers, the strictness of which may hinder free competition on all levels. For example, wholesalers must store at least 90 per cent of existing medicines. In the former version of the text, this obligation was, in itself, likely to prevent manufacturers from freely organising their own supply chain. The changes adopted in September 2012 now bar the possibility to implement in France, at least on a large and systematic scale, some of the schemes that have been implemented in

other European countries, in particular in the UK. The new text indeed imposes on the pharmaceutical firms the obligation to supply the French wholesalers so they are in a position to meet their own public service obligations.

Such obligation is now legislative in nature. The Law of 26 January 2016 further introduces article L 5121-29 of the PHC, according to which, marketing authorisation holders shall appropriately and continuously supply all authorised pharmaceutical wholesalers in order to enable them to fulfil their public service obligations as well as implement shortage management plans.

Additionally, in the supply chain, wholesale and retail upper margins are set by the government, again eliminating competition.

Most importantly, within the past 10 years, French law has been designed to support the inclusion of generic products into the market. Initially, generics benefited from article L 5125-23 of the PHC allowing pharmacists to replace prescribed brand-name medicines with their generic equivalent. Since 1 January 2009, general practitioners are required to write their prescriptions according to the international non-proprietary names, which assign a common name to each active substance. This mechanism is promoted through financial incentives to pharmacists. Indeed, their margins are set higher by the government when they sell generics to their patients. Furthermore, under the French Social Security Code, generic companies are allowed to grant much higher discounts than originator companies to pharmacists. Thus, where originator companies' discounts to pharmacists are limited to 2.5 per cent, generic companies were allowed to grant them discounts of up to 17 per cent. However, in practice, generic companies did not respect these thresholds and implemented various mechanisms in order to actually grant financial advantages that could, in fact, go up to almost 50 per cent. Taking account of this situation, parliament amended this cap (Law dated 17 March 2014). From 1 September 2014, generic companies may grant pharmacies discounts of up to 40 per cent on their reimbursed products.

As a counterpart of this change, the Law imposes on generics companies an obligation to notify to the CEPS the annual turnover they achieved for each medicine, together with the global discounts and financial advantages granted to pharmacists for each medicine. In the case of absence of filing or false declaration, the generics company may incur a fine of up to 5 per cent of the concerned annual turnover.

It is likely that the information thus gathered would be used by the pricing Authority to obtain prices reductions from the generics companies if it shows that discounts granted to pharmacies are of significant importance.

Finally, on 4 May 2012, the Ministry of Labour, Employment and Health set a mandatory objective of national market penetration rate of generics at 85 per cent for 2012. With an actual rate of 83.7 per cent on 31 December 2012, this goal was almost achieved. Since then, the rate has been set out at 85 per cent each year. The setting out of such rate also limits competition, even between generic and originator companies, since it restrains, in any case, the originator company's market share to a maximum of 15 per cent.

Competition legislation and regulation

4 Which legislation sets out competition law?

The competition legal framework is mainly codified in Book IV of the French Commercial Code, entitled 'Pricing freedom and competition' (article L 410-1 and following), lastly amended by Law No. 2008-776 on the Modernisation of the Economy and passed on 4 August 2008.

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

There is no specific authority in charge of applying competition law in the pharmaceutical sector. Competition law is applied to this sector by the Competition Authority, which is also competent for all business sectors.

As of 2 March 2009, the former Competition Council was transformed into a renewed Competition Authority.

The Authority is now solely responsible for making competition work on the markets by overseeing mergers as well as by enforcing rules prohibiting cartels, anticompetitive agreements and abuses of dominance in any economic sector.

In particular, the Authority is responsible for merger control. Filing is mandatory, when the conditions set out in article L 430-2 of the French Commercial Code are met (namely thresholds of total turnover).

Pursuant to article L 430-7-1 of the French Commercial Code, the Minister of the Economy nonetheless retains certain powers such as opening an in-depth stage II investigation or reversing the Competition Authority's decision under certain circumstances.

Since the replacement of the Competition Council by the Competition Authority, competition investigations are mostly conducted by the investigators of the Competition Authority, under the sole supervision of the chief case-handler. However, the Ministry of the Economy holds some powers in this regard through its administration, which still has some investigators.

In April 2014, the Competition Authority opened an investigation for anticompetitive agreements between Roche and Novartis. On 26 October 2016, the French Supreme Court approved the decision authorising the Directorate-General for Competition, Consumer Affairs and Prevention of Fraud to carry out dawn raids in the premises of Novartis.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

There are no particular remedies for the pharmaceutical sector that may be imposed by the Competition Authority.

The sanctions for infringements of French competition law are various: the Competition Authority may order interim measures, order the parties to change their conduct within a specified period or under special conditions, order publicity measures for its decisions or sentence parties to fines of up to 10 per cent of their worldwide turnover.

French competition law also provides alternative means to resolve competition issues to companies suspected of infringement.

Firstly, before notifying an actual statement of objections, the Authority may indicate to a company it has 'competition concerns' regarding some of its behaviour. The said company may then propose commitments in order to resolve such concerns and thus avoid being fined.

Furthermore, even having received a statement of objections, companies may initiate a settlement procedure enabling them to obtain a fine reduction of between 10 and 25 per cent if they agree to waive their right to challenge the statement of objections and propose behavioural or structural commitments. A new law, adopted in August 2015, adjusted this settlement procedure to render it closer to the one existing at the European level. This procedure would be rendered more 'attractive', since the general case handler will from now on be in a position to propose in the settlement the minimum and maximum fine the firm must pay, should it decide to sign the settlement.

Finally, French law also provides a leniency programme under which companies may report anticompetitive practices to the Authority before or after the opening of a contentious procedure against them. They may thus obtain either full immunity or a reduction of the fine they would otherwise have incurred in consideration for handing over evidence to the Authority and for their cooperation during the investigation phase.

These solutions have been implemented in the pharmaceutical sector. As regards financial sanctions, in Decision No. 07-D-09, the Competition Authority imposed a €10 million fine on GlaxoSmithKline as it ruled that the firm had abusively hindered the entry of generics into hospitals by implementing predatory prices as part of a global intimidation strategy aimed at discouraging generic medicine manufacturers from entering the hospital medicine market. However, the decision was overruled by the Supreme Court in a Decision dated 17 March 2009.

More recently, in Decision No. 13-D-11, the Competition Authority imposed a €40.6 million fine on Sanofi-Aventis for having implemented a strategy that denigrated generics of Plavix, one of the top-selling medicinal products in the world. The Paris Court of Appeal followed by the French Supreme Court confirmed the decision and the fine imposed by the Competition Authority, in cases dated 18 December 2014 and 18 October 2016. In three decisions, Nos. 07-D-22 (*Boehringer Ingelheim, Lilly France, Merck, Sanofi-Aventis*), 07-D-45 (*Pfizer*) and 07-D-46 (*GlaxoSmithKline*), the Competition Authority accepted the commitments submitted by pharmaceutical companies that amended

their supply chain for medicinal products so as to increase its fluidity, flexibility and transparency for wholesalers. These decisions were ultimately overruled by the Supreme Court on procedural grounds.

In Decision No. 13-D-21, Schering-Plough was fined €15.3 million for hindering the entry of generics of its originator, Subutex. Schering-Plough chose not to contest the objections brought forward by the Competition Authority and submitted several commitments in order to prevent such practices in the future, such as the control of commercial strategy before the entry of generics, and the sales staff training on the prohibition of denigration of generics. In this respect, the amount of the fine was reduced by 20 per cent. In its decision of 26 March 2015, the Paris Court of Appeal dismissed Reckitt Benckiser (fined 318,000 euros for its participation in the anticompetitive agreement) for annulment of the above-mentioned decision, a decision that was finally confirmed by the French Supreme Court on 11 January 2017.

Moreover, following the example of the European Commission of 2006, the Competition Authority published a Notice on the Method Relating to the Setting of Financial Penalties (16 May 2011), which provides a thorough analysis of the elements taken into consideration for the setting of the amount of fine.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Private parties can initiate proceedings before the Competition Authority by filing a complaint.

They usually request the Competition Authority to take interim measures to order the end of the practices they deem to be anticompetitive (see, for example, Decision No. 07-D-22 *Phoenix Pharma*, Decision No. 09-D-28 *Ratiopharm*, Decision No. 07-MC-06 *Arrow Génériques*). In the latter, based on a few pharmacist testimonies, the Competition Authority considered that Schering-Plough may have denigrated Arrow's generic. It thus adopted interim measures in order to restore the healthcare professionals' confidence towards Arrow's generic and ordered Schering-Plough to publish a statement in this regard.

The executive order No. 2017-303 of 9 March 2017 (OJ of 10 March 2017) finally transposed into French law, Directive 2014/104/EU of 26 November 2014, certain rules governing actions for damages under national law for infringements of the competition law provisions of the member states and of the European Union. This text aims at promoting private enforcement (eg, recognising irrebuttable presumption of misbehaviour in case of an infringement of competition law found by a final decision of a national competition authority or a review court, shifting the burden of proof onto the defendant as regards the overcharge passed on, and the right to full compensation of the claimant.)

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

Regarding competition inquiries, the powers of the Competition Authorities are very similar to those of the European Commission. Since the reform of competition investigations, the Competition Authority has its own investigators (see question 5) in order to conduct ordinary investigations (article L 450-3 of the French Commercial Code) or investigations under judicial control (article L 450-4 of the French Commercial Code).

On 25 February 2013, the Competition Authority launched a broad sector inquiry to investigate the distribution of human medicinal products 'in town'. After a first phase of discussions with all stakeholders (pharmaceutical companies, wholesalers and importers, trade unions, governments, councils of pharmacists and physicians, consumer groups, representatives of the retail sector), the Competition Authority issued in July a preliminary report, which was extensively commented on by numerous stakeholders.

The final report was published on 19 December 2013 (opinion 13-A-24) and comprised various comments and proposals as regards each link of the supply chain, with the aim of 'enhancing competition within this highly regulated industry'.

As regards the originator companies, the main findings can be summarised as follows.

In 2013 the Competition Authority specifically punished the behaviour of originator companies denigrating generic medicinal products in the pharmaceutical sector (see question 6). In this regard, the final report insists that pharmaceutical companies adopt, beyond and within a compliance programme, a specific training programme for the whole staff of the company on the 'denigration issues and risks', in order to avoid 'denigration barriers' whenever generic products are about to enter the market.

In this respect, every originator company active on the French market should investigate and assess the possible necessity of finally adopting a competition compliance programme or amending its existing programme in this regard, if necessary.

The final report indirectly alludes to supply chain management schemes through the issue of supply shortages, which arose in France in 2012 and 2013. The Authority implied that such shortages might have several different causes, but observed that these shortages might be the consequence of supply chain management schemes implemented by pharmaceutical companies, as well as the activity of the wholesalers exporting these products.

In addition, it is to be noted that the report only addresses the issue of the direct to pharmacy (DtP) channel by mentioning that it 'remained a minority channel'.

Finally, the Competition Authority commented on the relationships between originator companies and wholesalers only in relation to non-reimbursable medicinal products (OTC medicinal products). The report noticed that, for these medicinal products (for which rebates are not limited by legal provisions, see question 3), in some cases, rebates granted to pharmacists through the DtP channel seemed to be superior to the ones granted to the wholesalers. Such difference would 'illustrate the power struggle created by the pharmaceutical firms with the wholesalers'. The Authority suggested that the situation could result from the companies' willingness to maintain their margins in relation to the smaller pharmacies, since they would nevertheless keep an interest in buying from the pharmaceutical company rather than through wholesalers.

Even if, in practice, such behaviour is not limited to non-reimbursable medicinal products, it is to be kept in mind that, in itself, such behaviour would not constitute an anticompetitive practice. The situation depends on the context as well as differentiated and specific conditions applied to both channels.

Other possible anticompetitive aspects of the commercial policy of pharmaceutical companies are not directly addressed by the final report. Tied rebates are solely mentioned as part of the commercial policy of companies selling, on the one hand, generic products and, on the other hand, non-reimbursable medicinal products.

Nevertheless, pharmaceutical companies should audit their commercial policy in this respect in order to suppress any risk or even potential abuse of dominant position.

As regards the wholesaler link, the Report does not raise actual competition concerns and simply indicates that a risk of coordination between these players cannot be excluded without giving any tangible element that could have led to such mention (except for the fact that the wholesalers have been fined by the Competition Authority some years ago on such ground; see the French Competition Authority decision *OCP Répartition, Alliance Santé*, CERP Rouen No. 01-D-07).

Finally, with respect to retail sales, the Report notes that despite the strong growth of the self-medication practice, competition between pharmacies in this sector is very weak. Thus, the Authority recommended that the government should adopt measures to implement a limited and regulated opening to competition for self-medication medicines and that certain products, such as pregnancy tests and contact lens care solutions, should be taken out of the scope of the pharmacists' monopoly in order to also be distributed in drugstores or supermarkets. For the last two categories, the laws have been changed accordingly, whereas the distribution of self-medication products outside the pharmacies is still the subject of strong dispute.

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

Article L 462-1, paragraph 2 of the French Commercial Code enables professional associations, labour unions or recognised consumer groups to petition the Competition Authority with regard to the

interests for which these are responsible to obtain its opinion on 'any issue regarding competition'.

This option has been used mainly by healthcare professional associations. For example, the national association of emergency practitioners requested the Competition Council's opinion on rules set out by the Council of the national medical association to organise emergency care in France (Opinion No. 96-A-17 dated 5 November 1996).

This opportunity has recently been used by manufacturers' associations. Thus, the French National Association of Dental Prostheses Manufacturers consulted the Competition Authority regarding the effects on competition of the exclusive sale of dental prostheses by dental surgeons (Opinion No. 12-A-06 dated 29 February 2012).

The Association of Veterinary Medicinal Products Manufacturers also used this faculty to obtain the Competition Authority's opinion regarding the possible competition issues that would result in the creation of an association of veterinary surgeons whose goal was to negotiate prices with the manufacturers on behalf of their members. The Authority concluded that the appearance of this newcomer would not by itself raise issues from a competition law standpoint (Opinion No. 12-A-14 dated 19 June 2012).

Review of mergers

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

Due to the size of most pharmaceutical firms, the majority of mergers in this sector are referred to the Commission, as European thresholds are often exceeded. On this point, the Commission is currently considering complementing the existing thresholds (turnover-based system) with the notion of 'market potential' in order to capture some transactions, particularly in the pharmaceutical sector.

This being said, French practice in this sector is thus limited. However, specific sector features are taken into account in the definition of the relevant markets.

For example, the Competition Authority authorised a merger between Boiron and Dolisos, two French companies manufacturing homeopathic products (Opinion No. 05-A-01).

In this case, the definition of the relevant markets was influenced by the regulations applicable to certain products. The Competition Authority distinguished within the homeopathic medicines, generic homeopathic medicines (MNC) from branded homeopathic medicines (MNM), based, in particular, on the facts that the MNM include, contrary to the MNC, a therapeutic indication and are not reimbursable by social security insurance, their marketing is thus subject to a marketing authorisation, and their prices and margins are not controlled.

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

Product market

In general, medicinal products may be subdivided into therapeutic classes by reference to the 'anatomical therapeutic chemical' classification (ATC), which classifies medicinal products into five different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.

The third level (ATC3) allows products to be grouped in terms of their therapeutic indications (ie, their intended use) and is therefore generally used as an operational market definition. However, market definition may also be based on other levels of the ATC classification.

As regards merger control, the French authorities' practice regarding the market definition is mainly guided by the European Commission case law regarding the pharmaceutical sector. Nevertheless, it should be noted that in antitrust cases, the Competition Authority considers level 3 of the ATC merely as a starting point and tends to narrow the market definition to level 5 of the ATC, namely, the molecule (see Decisions No. 03-D-35, *Sandoz*, No. 07-D-09, *GlaxoSmithKline*, No. 09-D-28 *Ratiopharm*, Decision No. 07-MC-06 *Arrow Génériques*). This trend is also visible in merger controls. In a recent decision, the Competition Authority had to assess possible effects of a merger on the market of regulators of bone calcium (acquisition of sole control of Warner Chilcott Company by Actavis Inc, Decision No. 13-DCC-106), a market that has been examined four times by the Commission between 2008 and 2010 (No. COMP/M.5295, *Teva/Barr*, 19 December 2008, No. COMP/M.5253, *Sanofi-Aventis/Zentiva*, 4 February 2009 and No. COMP/M.5555, *Novartis/EBEWE*, 22 September 2009, No. COMP/M.5865 *Teva/Ratiopharm*, 3 August 2010). In each case, the European authority left open the issue of whether the market should be defined at level 3 (regulators of bone calcium) or level 4 (bisphosphonates), but clearly ruled out the idea of narrowing the market at level 5, deeming that there was a high degree of substitutability between the molecule (risedronic acid) and the other bisphosphonates. Nevertheless, the Competition Authority checked the market shares of the parties to the concentration on each of the three levels.

On the other hand, the Competition Authority conforms to the Commission's practice as regards the definition of the different market products and distinguishes between prescribed medicines and non-prescribed medicines, reimbursable and non-reimbursable medicines, products already on the market and pipeline products, active pharmaceutical ingredients, contract manufacturing. In the *Boiron/Dolisos* case, the Competition Authority made its own distinction between MNC and MNM (see question 10).

Geographic market

The geographic market for pharmaceutical products is generally defined on a national scope (see Decisions No. 07-MC-06 and 07-D-09) but may sometimes be said to be local. It could be the case for the market related to the supply of medicinal products by wholesalers to pharmacists (due to public services obligations; see question 3), contrary to the market supply of medicinal products by pharmaceutical firms to wholesalers, which is on a national scope (Opinion No. 02-A-15 on a merger between two pharmaceutical wholesalers).

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

Article L 420-4 of the French Commercial Code lays down a system of exemptions that states that provisions related to cartels and abuse of dominant position do not apply to practices that have the effect of promoting economic progress and reserve for consumers a fair share in the resulting profit, without giving the undertakings involved the opportunity to eliminate competition for a substantial part of the products in question.

For example, in Decision No. 07-D-05, the Competition Authority admitted that the price method set out by a trade association to determine the price of non-reimbursable prostheses did not infringe the provisions of article L 420-1 of the French Commercial Code, as the conditions of exemptions were fulfilled. The method allowed patients to benefit from rare devices under better conditions.

As regards mergers, the Ministry of the Economy may reverse the decision taken by the Competition Authority on the grounds of general interest other than the maintenance of competition, notably industrial development, the competitiveness of companies with regard to international competition or the preservation of employment.

In the pharmaceutical sector as in other sectors, arguments such as strengthening the local or regional research and development activities are almost never admitted by the competition authorities.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

The French Competition Authority has to ensure the operation would not harm competition, especially by the creation or the reinforcement of a dominant position or the creation or reinforcement of a purchasing power that would place the supplier in a position of dependency. In this regard, the Authority first has to determine the relevant markets and the conditions under which those are affected.

Thus, under French Law, overlaps may be considered problematic when a market is deemed to be 'affected', that is, if one of the following three conditions is met (annex 4-3 of article R 430-2 of the French Commercial Code):

- two or more concerned undertakings operate on this market and their cumulative shares amount to 25 per cent or more;
- at least one of the concerned undertakings operates on this market and another of these undertakings operates on an upstream, downstream or related market, as soon as, in one or the other of these

markets, the market shares of all the parties amount to 25 per cent or more; or
- the transaction leads to the elimination of a potential competitor on one of the markets on which the parties operate.

These criteria are detailed in the guidelines related to merger control issued by the French Competition Authority on 10 July 2013.

When assessing the *Boiron/Dolisos* merger, the Competition Authority considered that the operation would not only affect the market but would create a near-monopoly in the market for MNC. Regarding potential competition, the Authority ruled that new entries would be unlikely, due to several barriers such as the regulatory framework, impossibility of competing on prices, range effect, low level of prices and substantial registration fees for new products.

According to article L 430-6 of the Commercial Code, the Competition Authority also assesses whether the contribution to economic progress is such to offset the distortions of competition that may arise from the operation.

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

The few mergers in the pharmaceutical sector controlled by the French authorities did not imply pipeline products. However, it is likely that in such cases they would apply general rules. Overlaps between pipeline products would be assessed regarding the competition situation on the relevant markets and possible effects of the merger on these markets. It cannot be excluded that in case of serious doubts, the Competition Authority could authorise the merger, provided that rights on one product would be licensed if finally launched.

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

Like the European Commission (see decision of December 2014 in the *IMS Health/Cegedim* deal), the French Competition Authority is likely to require commitments from the parties, such as licensing or divestments (even if such remedies have not been required yet in the pharmaceutical sector).

In the *Boiron/Dolisos* case, the merger was authorised after the parties guaranteed that the new entity would continue to offer every homeopathic strain both parties offered before the merger, and that they would not grant financial incentives to pharmacists in exchange for exclusive purchasing commitments of MNC, or grant financial incentives to pharmacists buying MNC in exchange for a commitment to also buy their branded homeopathic medicines.

Notably, a new law adopted in August 2015 gave more power to the French Competition Authority in this regard. The Authority is now entitled to impose penalties on companies for not implementing remedies or commitments conditioning the implementation of the merger.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

In this regard, French law and practice by the authorities are quite similar to EU law and practice. Acquisition of assets falls within the meaning of 'control'. As with EC Merger Regulation No. 139/2004, the French Commercial Code (articles L 430-1, I, 2 and L 430-1, III) provides that the object of control can be one or more, or also parts of, undertakings that constitute legal entities, the assets of such entities, or only some of these assets.

Thus, in its new guidelines related to merger control dated 10 July 2013, the Competition Authority states that the acquisition of control over assets (such as brands or patents) can only be considered a merger if those assets constitute the whole or a part of an undertaking, namely a business with a market presence, to which a market turnover can be clearly attributed (see paragraph 22 of the guidelines).

Anticompetitive agreements

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

Agreements or concerted practices fall under the scope of article L 420-1 of the French Commercial Code, which is similar to article 101 of the Treaty on the Functioning of the European Union (TFEU) (formerly article 81 of the EC Treaty). It specifies that practices that have the aim or that are likely to have the effect of preventing, restricting or distorting competition in a market shall be prohibited, even through the direct or indirect intermediation of a company in the group established outside France, and in particular those that:
- limit access to the market or the free exercise of competition by other undertakings;
- prevent price fixing;
- limit or control production, opportunities, investments or technical progress; or
- share out the markets or sources of supply.

18 To what extent are technology licensing agreements considered anticompetitive?

The French Commercial Code does not contain provisions applicable to technology licensing agreements. Thus, such agreements are assessed in accordance with the rules laid down in EC Regulation No. 772/2004 on technology transfer (see the Competition Council's Annual Report, 2004, p 125).

Licensing agreements would consequently not be deemed as anticompetitive, subject to the conditions that the parties' market shares meet the thresholds set out by the Regulation and that they do not contain hard-core restrictions as listed by the Regulation.

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

French legislation does not contain specific provisions applicable to co-promotion and co-marketing agreements. Thus, the Competition Authority's review of such agreements follows European legislation and practice.

The Commission defined co-promotion and co-marketing agreements in its Final Report on the pharmaceutical sector inquiry (8 July 2009) as being:
- co-promotion agreements: (joint) commercialisation of a specific medicinal product by both parties under one single trademark; and
- co-marketing agreements: commercialisation of a specific medicinal product by both parties under different trademarks.

Such definitions may appear to be clear in first instance. However, assessment of such contracts under competition law is often problematic as the relationships they create between the parties may fall under the scope of various regulations and guidelines (vertical and horizontal agreements, R&D, transfer of technology agreements).

The content and nature of the relationships created between the parties have to be carefully scrutinised in order to determine under which set of competition rules a particular agreement may fall into and, consequently, assess its validity under competition law, in particular if they imply exchanges of information between the parties.

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

Agreements focusing on R&D create a collaborative relationship between two companies in which they contribute to the overall discovery process by using the parties' combined expertise to deliver outcomes. R&D agreements often contain a transfer of technology (see question 18).

Other agreements (as listed in the final report of the European Commission, such as consignment stock agreements, agreements focusing on the transfer of a market authorisation or the underlying documentation) could contain direct or indirect restrictions such as price fixing or territorial restrictions.

All these agreements often contain confidentiality provisions related to information exchanged between parties. However, these provisions should not and cannot obstruct the application of competition rules so that they may not be upheld in case of antitrust infringements.

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

The Competition Authority uses the principles set out in EC Regulation No. 2790/1999 (now EC Regulation No. 330/2010 of 20 April 2010) to

apply French competition law to vertical agreements, if the relevant market share does not exceed the 30 per cent threshold. In this regard, the negative effects on the market that may result from vertical agreements are as follows:

- foreclosure of other suppliers or other buyers by raising barriers to entry;
- price fixing (see Decision No. 07-D-35, *Sirona Dental Systems*);
- reduction of interbrand competition; and
- limitations to the freedom of consumers to purchase goods or services in a member state.

In this respect, the Authority had the opportunity to assess vertical agreements in many decisions. It deemed that, under certain circumstances, in particular when having small market shares, approval of its wholesalers by a pharmaceutical firm shall not be prohibited (see Decision No. 03-D-53, *Biotherm*).

Furthermore, the Authority ruled that the prohibition of mail-order selling imposed by a prosthesis manufacturer to its wholesalers did not restrict competition law (see Decision No. 03-D-69, *Ivoclar*). However, this case law would no longer apply since, according to the Court of Justice's decision in the *Pierre Fabre* case (Case C-439/09, *Pierre Fabre Dermo-Cosmétique SAS*), the Paris Court of Appeal ruled, on 31 January 2013, that prohibition to sell on the internet constitutes a per se restriction to competition when the clause contains no objective justification with respect to product properties.

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

There is no French case law concerning the settlement of a patent dispute in the pharmaceutical sector in relation to an antitrust violation.

The Commission's final report on the sector inquiry suggested that, under certain circumstances, settlement agreements between originator and generic companies could be deemed to be anticompetitive. Following this statement, the Commission sent several statements of objection to pharmaceutical firms and fined Lundbeck (€93.8 million), Johnson & Johnson (€10.8 million) and Novartis (€5.5 million) as well as Servier (€331 million).

Owing to the conclusion of a co-promotion agreement, Johnson & Johnson provided Novartis with monthly payments exceeding the profit that the company would have expected to obtain from selling its generic on the market.

Servier implemented a strategy to exclude competitors and delay generic entry through a technology acquisition and a series of patent settlements.

In the *Lundbeck* case, the agreements went further than other settlements of patent disputes as the originator company not only paid significant lump sums to generic companies, but also purchased their stocks for the sole purpose of destroying them, and guaranteed them profits through a distribution agreement. Therefore, Lundbeck kept the generic producers out of the market for the duration of the agreements without promising the generic companies any guarantee of market entry thereafter.

For the first time, on 8 September 2016, the General Court ruled on the pay for delay practice in the *Lundbeck* case. In line with the Commission, the General Court acknowledged the restriction by object and confirmed the existence of potential competition between generic and originator companies, although the intellectual property rights on the patent had not expired.

However, it appears that potential antitrust violation by such settlements may only be discussed in cases where the settlements would contain provisions preventing the generic company to enter the market and providing for a kind of value transfer.

The seventh report on the Monitoring of Patent Settlements published on 13 December 2016 showed a total of 125 patent settlements for the year 2015, where B.II agreements (settlements limiting generic entry with value transfer from originator to generic company) from originator to generic company accounted for 10 per cent.

In the US, some circuit courts first ruled that patent settlements that would not go further than the potential exclusionary effect that is the essence of the rights conferred to the holder by the patent itself (the patent test) did not infringe competition law, even when providing for a transfer of value from the originator company to the generic firm in compensation for the latter not entering or delaying its entry into the market.

However, in a decision dated 17 June 2013 (*Federal Trade Commission v Actavis Inc*), the Supreme Court dismissed the patent test and ruled that the probability for a reverse payment to be deemed anticompetitive depends on the size of the reverse payment, its relationship to projected litigation costs, the existence of convincing justification and the predicted magnitude of the harm.

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

The pharmaceutical sector in France is already very transparent. Most pharmaceutical firms are members of the Group for the Development and Study of Statistics (GERS), an independent body to which they supply their sales data for each medicine, in each galenic form, they market in France. Firms may buy the compiled sales data, including information from all the other firms, from the GERS. As a result, any given firm can be in a position to have a clear picture of the sales of all its competitors on the French market.

It is also true that in France, as in other EU member states, additional measures intended to impose transparency at all levels of the pharmaceutical sector have been adopted in the past few years.

As in several other countries, and especially in the aftermath of the Mediator scandal, the PHC has been amended to provide for more transparency in the relationships between the industry and the HCPs. In this regard, article L 1453-1 of the PHC as modified by the Law of 26 January 2016 provides for mandatory transparency and disclosure of contractual relationships (the date of signature, the precise subject matter, the amount of the agreement, the direct and final beneficiaries) on a 'single site' published by the French government. Deliberate failure to comply with this publication is punishable by a fine of up to €75,000.

The Law of 26 January 2016 has significantly changed the way companies publish their business links. The Decree No. 2016-1939 of 28 December 2016 implementing such new provisions will come into force on the date of publication of the executive order amending the one concerning the conditions for the functioning of the 'single site', that is, at the latest on 1 July 2017.

It is to be noted that other instruments aim or result in increasing transparency as regards other areas in the pharmaceutical sector. Thus, it is to be noted that, pursuant to article L 162-17-4 of the Social Security Code, the new agreement (the Framework Agreement) signed between the CEPS and the French Pharmaceutical Companies Association on 31 December 2015, includes an article 2 entitled 'Exchanges of Information'. This contains a lot of information and includes, notably, the pharmaceutical firms sales data (through the GERS), the actual use of medicines by public hospitals, monitoring of the reimbursement expenses and the cost of legal obligations weighing on the pharmaceutical firms (eg, management of waste, packaging and out-of-date medicines, post marketing studies and shortfall management plans).

The Framework Agreement now also provides that pharmaceutical firms shall supply an ad hoc committee with 'prospective' data related to the arrival of breakthrough therapies for as long as they may impact reimbursement or the organisation of healthcare services. The said data are, of course, deemed to be confidential.

Furthermore, the renewed Agreement on sales representation provides that each pharmaceutical firm shall conduct an inquiry on the quality of its promotional activity for its most promoted medicine every year. The data will be anonymised before being published, and such publication will provide important qualitative information to all pharmaceutical firms as regards their competitors' promotional practices.

Last but not least, the Law 'Sapin II' (Law of 9 December 2016) introduced a very new system for the prevention and repression of corruption involving heavy management constraints for companies, subject to new criminal sanctions. The central provisions mainly consist of the creation of a new Corruption Prevention Agency with expanded and innovative missions and powers, a new whistle-blower system with the obligation for companies of at least 50 employees to implement appropriate procedures for the collection of alerts, an obligation for certain companies to implement procedures for the prevention of corruption no later than 1 June 2017 and the creation of a Register for

Interest Representatives that will have a major impact on businesses. These examples show that the pharmaceutical sector is becoming more transparent than it ever has been. From a competition point of view, such transparency reduces the uncertainty and renders the competitors' behaviours easier to predict. However, since it results from government-imposed measures, it is not, in itself, anticompetitive.

It cannot be overlooked that, at some point, certain firms would nevertheless be tempted to go further in terms of exchange of information.

Anticompetitive unilateral conduct

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

Any conduct aimed at limiting access to the market or competition is likely to be considered abusive if it is carried out by an undertaking holding a dominant position (article L 420-2 of the French Commercial Code).

Abusive behaviour by a dominant firm may consist of a refusal to sell, tying, discriminatory conditions of selling and breach of commercial relationships, or denigration of generic medicinal products.

For example, in Decision No. 03-D-35, the Competition Authority imposed a €7.8 million fine on Sandoz for abuse of dominant position by offering tied discounts. The firm proposed the hospitals discounts on its global sales to hospitals (especially sales of medicines that were deemed to be in a dominant position) on the condition that the hospitals undertook to buy other products for which the firm was competing with other pharmaceutical firms. The Authority considered that such a scheme resulted in increasing customer loyalty towards Sandoz.

The Competition Authority fined both Sanofi-Aventis (in Decision No. 13-D-11) and Schering-Plough (in Decision No. 13-D-21), for abusing their dominant position, notably by denigrating generic medicinal products. The Competition Authority ruled that such practices had the object and effect of restricting the generic companies' access to market. The Paris Court of Appeal confirmed the decision from the Competition Authority concerning the *Sanofi-Aventis* case and its decision for the *Schering-Plough* case is still pending (see question 6).

On 8 July 2014, the Competition Authority fined Cegedim, one of the medical database firms' leaders, €5.7 million for having refused to sell its database to pharmaceutical companies that were using another firm's software while such database was regarded by health-care professionals as being the ultimate system. This analysis was confirmed by the Paris Court of Appeal on 25 September 2015.

The investigation launched on 10 July 2014 into the optical glasses sector may implicate the firm that holds a near-monopoly in the optical glasses sector. A decision is still expected.

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

The French Commercial Code does not define dominant position. Under such circumstances, the Competition Authority applies the definition set out by the European Court of Justice in the *United Brands* case (27/76), that is, where an undertaking has the faculty to behave independently of its competitors, customers, and ultimately from consumers. The main indicator of dominance is, of course, a large market share; other factors include the economic weakness of competitors, the absence of latent competition and control of resources and technology.

The Competition Authority follows European case law in its assessment of these situations. However, in a decision dated 14 January 2010, although it left the question open, the Competition Authority surprisingly seemed to consider that, despite important market shares of 55–60 per cent in 2000 and 70–75 per cent in 2004, Sanofi-Aventis may not have held a dominant position in the hospital medicines market (see Decision No. 10-D-02).

Regarding joint domination, the Competition Authority applies the conditions set out by the Court of First Instance (now the General Court) in the *Irish Sugar* case (T-228/97), that is, factors connecting the undertakings that give them the power to adopt a common market policy.

The Competition Authority has never found a joint domination in the pharmaceutical sector (see Decision No. 07-D-42, *Nestlé, Danone-Blédina, Milupa-Nutricia, Sodilac*). The issue was addressed again recently by the Ministry of the Economy when referring to the Competition Authority a case of alleged concerted practices and abuse of a joint-dominant position by Ethicon and Tyco Healthcare. However, the Competition Authority did not rule on the issue of joint domination as it deemed that the practices of the undertakings concerned were not anticompetitive (see Decision No. 09-D-38).

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

Under French competition law, in theory, ownership of a patent does not systematically confer a dominant position to the holder, but under certain circumstances, the Authority deems that it may create or reinforce the dominant position of a company, in particular because this intellectual property right has 'itself an economic force'. Such position was reasserted by the Competition Authority in its Annual Report for 2004.

As mentioned above (see question 11), it is worth noting that, in antitrust cases, the French Competition Authority tends to narrow the market definition to level 5 of the ATC medicinal product classification, namely, the molecule.

In its Decision No. 96-D-12, confirmed by the Supreme Court, the Competition Authority deemed that from 1987 to 1991, Lilly France held a dominant position on the Dobutrex market. The firm had an exclusive right of distribution of Dobutrex as it held a patent on the medicine.

Since then, French competition authorities have almost always defined the relevant market as being the one of the molecule without real verification of the therapeutic use of the medicines on the market, thus establishing an almost automatic link between patent and dominant position.

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

In 2001, the Competition Authority ruled that the mere application for the grant of a patent was not abusive, since such conduct would not be capable of harming competition (see Decision No. 01-D-57).

However, it is to be kept in mind that in the *AstraZeneca* case (judgment dated 1 July 2010, case T-321/05), the General Court upheld the Commission's decision that ruled that the mere application for a supplementary protection certificate could amount to an abuse (see Decision dated 15 June 2005). On 6 December 2012, the ECJ confirmed the General Court's decision (case C-457/10P). Furthermore, in its final report on the pharmaceutical sector inquiry, the European Commission identified practices, called 'patent filing strategies', suggesting that filing numerous patent applications for the same medicine (forming the 'patent clusters') could, in itself, delay or block the market entry of generic medicines.

Under such circumstances, it is unclear whether the Competition Authority would hold to its former ruling regarding patent application, or evolve in the direction set out by the European authorities.

Prima facie, enforcing one's patents against parties infringing them is a legitimate procedural dimension of the material right granted to the patent holder.

In its final report, the European Commission alleged that in certain instances, originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.

However, for the time being, European case law considers that court proceedings may constitute an abuse only in exceptional circumstances (see criteria set out by the Court of First Instance (now the General Court) in its *ITT Promedia NV* case). This case law is also applied in France. The Competition Council ruled that the mere fact of a dominant undertaking to defend its intellectual property rights before the competent courts may not be seen as an abuse per se (see Decision No. 01-D-57).

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

Such strategies may consist of, for the originator companies, the launch of second-generation products or the follow-on of medicinal products shortly before the loss of exclusivity of the first-generation product, sometimes combined with the withdrawal of the initial product from the market and withdrawal of the MA. The European Commission

considered that AstraZeneca abused its dominant position for having implemented such practices with its medicine Losec (see question 27). This decision was upheld by the General Court (judgment dated 1 July 2010, case T-321/05) and then confirmed by the ECJ (judgment dated 6 December 2012, case C-457/10P). In its final report, the Commission stated that as a result of such strategies, generic companies may encounter some difficulties to sell their generic products.

The ECJ has already had the occasion of ruling on such practices from a regulatory and parallel import point of view (ECJ, C-94/98 *Rhone Poulenc Rorer*). It acknowledged the possibility for a pharmaceutical company to withdraw its MA 'at any point in time without being obliged to give any reasons', setting out the principle that 'the concept of compulsory licensing is unknown in any Community pharmaceutical legislation'.

Furthermore, the General Court has set out the limits within which 'an undertaking in a dominant position enjoys an exclusive right with an entitlement to agree to waive that right', considering that such undertaking 'is under a duty to make reasonable use of the right of veto conferred on it by agreement in respect of third parties' access to the market' (CFI T-24/93, *Compagnie maritime Belge Transport SA v Commission*).

Thus, life-cycle management strategies may be deemed anticompetitive only if they result in hindering other undertakings, in particular generic companies. For example, such a decision was rendered on 3 September 2012 by the Regional Administrative Tribunal for Latium that reversed the Italian Competition Authority's decision to fine Pfizer Group €10.6 million for having implemented a multifaceted strategy to prevent the entry of generic producers.

However, for the time being, the French Competition Authority did not have the occasion to rule on the conformity of such practices with competition law, whereas the English Office of Fair Trading issued a statement of objections against Reckitt Benckiser for having withdrawn Gaviscon from the market before generic entry and promoted the second-generation medicine. Reckitt Benckiser agreed to pay a £10.2 million penalty for abuse of dominance in October 2010.

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

The launch by an originator company of a generic of its own medicine or to grant a licence shortly before the expiry of the protection of a patent with the intention to allow an 'early entry' has been a common practice in the pharmaceutical market for many years. In its final report, the European Commission states that early entry agreements are used to control the market launch of a generic product.

In France, there is as yet no case law regarding the practice of authorised generics.

In principle, it is not possible to consider such practices as anticompetitive per se. Such a statement would only be justified after an in-depth analysis of each contractual provision and of the possible effects on competition and consumers. In this regard, it is worth noticing that, in its report on authorised generics, the FTC noticed that such early entry could have a positive impact on consumers and the healthcare system.

In this sort of context, the originator firm should be able to demonstrate that the practice does not have any anticompetitive effects by preparing and implementing a competitive balance providing empirical evidence that the 'effect' and 'competitive balance' arrangement would be positive, the latter improving distribution of medicines within the relevant territory, while allowing consumers a fair part of the resulting benefit, without evicting competition for a substantial part of the medicines concerned.

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

Public health issues may be taken into account. In Decision No. 07-D-22, the Competition Authority admitted that quota systems adopted by some originator companies had the legitimate aim of rationalising production and optimising medicine distribution with regard to the country's needs, even if specificity of the sector has not been deemed sufficient to be considered as an objective justification that would allow, in itself, some practices to benefit from exemptions provided for by articles L 420-1 and L 420-2 of the French Commercial Code. While analysing the quota systems, the Competition Authority noticed that the restrictions imposed by the pharmaceutical firms on the wholesalers were limited to what was strictly necessary for a reliable and optimal supply of the French market, while maintaining real competition possibilities between wholesale distributors.

However, it should be noted that French decision practice could evolve based on more recent European case law. Thus, in the Spanish *GSK* case (ECJ, October 2009, *GlaxoSmithKline Services Unlimited*, C-501/06, C-213/06, C-515/06 and C-519/06), when examining the dual pricing schemes, the ECJ confirmed that the specific legal and economic context of the pharmaceutical sector could be relevant in the application of article 101(3).

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

An increase in national enforcement is not noticeable. To date, no decision has been rendered on such subject matter by the French Authority. In any case, since the EU sector inquiry and the systematic monitoring of patent settlements that has been carried out by the European Commission since 2010, pharmaceutical firms have become aware of potential competition issues and are more cautious when they contemplate entering into agreements with third parties in the context of upcoming generic entry.

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The laws covering the marketing and authorisation of pharmaceutical products are set out in the German Medicinal Products Act (AMG). The most recent significant changes of the AMG related to medicinal products for human use were made by the Third Law for Amendment of the AMG and other provisions, on 7 August 2013, to implement the changes resulting from Directive 2012/26/EU amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use. The Fourth Law for the Amendment of the AMG, adopted on 9 March 2016, transposes the changes resulting from Directive EU NO 536/2014 on clinical trials on medicinal products for human use, aiming to create an environment that is favourable for conducting clinical trials, with the highest standards of patient safety, binding for all EU member states. The main purpose is to simplify the rules governing the authorisation, conduct and monitoring of clinical trials.

With respect to generic drugs, there is no specific law regulating market entry or approval. The simplified approval procedure for generic drugs and access to innovators' documentation (*Bolar* clause) is set out in section 24b AMG. Accordingly, producers of generic drugs may refer to the innovators' documentation after eight years, beginning from the market authorisation of the innovators' product. Provided that the patent rights have lapsed, generic drugs that receive a marketing authorisation this way can enter the market after 10 years following the date of the first authorisation of the innovators' product. The period of 10 years can be extended by a maximum of one more year if, during the first eight years of authorisation, the marketing authorisation holder obtains authorisation for one or more new therapeutic indications that are held to bring significant clinical benefit in comparison with existing therapies.

Additional provisions regarding the marketing of narcotics are set forth in the Narcotics Act (BtMG), while the advertising of pharmaceutical products is governed by the Law on Advertising in the Field of Healthcare (HWG). As with the AMG, the latest significant changes have been made by the Third Law for Amendment of pharmaceutical and other regulations on 7 August 2013.

In addition to these federal laws – with regard to advertising to health professionals – a large part of the research-driven pharmaceuticals industry in Germany has agreed to comply with the FSA Code of Conduct on the Collaboration with Healthcare Professionals. The FSA Code of Conduct was revised in November 2013 in order to reflect recent requirements of the European Federation of Pharmaceutical Industries and Associations, and recognised by the Federal Cartel Office (FCO) in May 2014. Other pharmaceutical companies comply with the AKG Code of Conduct developed by the self-regulatory organisation 'pharmaceuticals and cooperation in the health care sector'. The AKG Code of Conduct was recognised by the FCO in September 2014 and amended in April 2015. Both codes – FSA and AKG – are based on the same recommendations and are, therefore, very similar. They cover mainly advertising to and cooperation with healthcare professionals, including medical sponsoring. Although the codes are only binding for member companies, a court may consider the rules as general practice even for non-members. However, according to a precedent of the Federal Court of Justice (BGH), it does not follow from the mere existence of a general practice that a behaviour deviating from such general practice would have to be regarded as unfair without further assessment. Sets of rules of (competitive) associations can therefore have, at best, an indicative significance for the question of unfairness.

Save for the price margins of wholesalers and pharmacies (see question 2), the pricing of pharmaceutical products in Germany is not directly subject to any price controls. Put differently, pharmaceutical companies are free to determine the prices of their drugs according to their discretion. However, this freedom is nowadays just theoretical, since the level of reimbursement can be (and very often is) set by various institutions (via guidelines of the Federal Joint Committee and the Central Federal Association of Health Insurance Funds). This is almost as effective as direct governmental pricing would be, since approximately 90 per cent of the population takes part in the effectively mandatory public health insurance system that reimburses pharmaceutical products. As a general rule – subject to exceptions – both private and public health insurers have to reimburse only the drugs that have the status of prescription-only medical products dispensed by pharmacies. The rules on the reimbursement of pharmaceutical products (mostly restricted to prescription-only medicines) are set out in volume V of the Social Insurance Code (SGB V).

Generally, antitrust issues relating to pharmaceutical products are subject to the rules of the Act against Restraints of Competition (ARC) and articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU).

The Federal Institute for Drugs and Medical Devices (BfArM) is the regulatory body for the authorisation of pharmaceutical products (except for biological pharmaceutical products) on the basis of the AMG. Its main task is to review the evidence in relation to efficacy, safety and adequate pharmaceutical quality of the pharmaceutical products in the course of the national marketing authorisation procedures. Marketing authorisations are limited to five years, after which, upon application and new evaluation, renewals may be granted. The BfArM also monitors the risks of pharmaceutical products already on the market. If it recognises frequent or serious side effects from a pharmaceutical product to an extent that the risks exceed the benefit of the drug, the BfArM will revoke or suspend the marketing authorisation.

The Paul-Ehrlich Institute (PEI) is the regulatory body for the approval and marketing of biological pharmaceutical products (such as vaccines for humans and animals, pharmaceutical products containing antibodies, allergens for therapy and diagnostics, blood and blood products and, more recently, tissue and pharmaceutical products for gene therapy, somatic cell therapy and xenogenic cell therapy). The power and duties of the PEI are comparable in scope to those of the BfArM.

Pursuant to the BtMG, the regulatory body for participation in the legal traffic of narcotics is the Federal Opium Agency, which controls the marketing authorisation holders, monitors manufacture, handling, trade and cultivation of narcotic drugs. Furthermore, it issues and distributes special prescription forms for narcotic and psychotropic drugs to physicians.

After a marketing authorisation has been granted, the surveillance authorities of the federal states are responsible for monitoring manufacturing facilities, controlling pharmaceutical products, seizing any

harmful products and preventing the marketing of potentially dangerous products. They will inform the regulatory bodies about potential risks arising from the marketing of pharmaceutical products.

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

With regard to pharmaceutical drugs that are dispensed by pharmacies and prescribed at the expense of the public health insurance (prescription-only medicines), the price margins of wholesalers and pharmacies are governed by the Ordinance on prices of pharmaceutical products (AMPreisV). Yet, the provisions of the AMPreisV do not set out actual prices. Rather, it regulates the maximum mark-ups, which may be charged by pharmacies and wholesalers on top of the sales prices of the pharmaceutical companies. Hence, the sale of prescription-only medicines is based on uniform retail prices consistent all over Germany. Contrary to the past German practice, the CJEU issued a landmark ruling in case C-148/15, *Deutsche Parkinson Vereinigung eV/Zentrale zur Bekämpfung unlauteren Wettbewerbs*, dated 19 October 2016, concerning the cross-border sale of prescription medicines online, after DPV requested to work with DocMorris, which offered lower prices for prescription-only medicinal products. The Court decided that German legislation on fixed retail prices for prescription pharmaceuticals is contrary to the free movement of goods as the regime constitutes a measure having an equivalent effect of a quantitative restriction, contrary to article 34 TFEU, and that the legislation is not justified by the aim of protection of public health, pursuant to article 36 TFEU. The matter has become a highly political issue for all market participants in Germany, especially for pharmacists, health insurance companies, wholesalers and patients. The consequence of the judgment may result from a complete ban of the online sale of prescription drugs to the abolition of uniform retail prices.

In addition, the wholesale distribution of medicinal products is based on the provisions of the German Ordinance on the Trade with Medicinal Products and the European Commission guidelines on Good Distribution Practice (GDP) of medicinal products for human use. The GDP guidelines, which were published in December 2013, are based on articles 84 and 85b(3) of Directive 2001/83/EC on the Community code relating to medicinal products for human use. They form an important foundation for pharmaceutical distribution quality management and contain instructions on issues such as premises and equipment, documentation of processes, transport, complaints, suspected falsified medicinal products and recall procedures.

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

The HWG contains the rules for advertising pharmaceutical products and the legal consequences of violating the rules. Among other measures, it contains provisions regarding misleading advertising. In the case of misleading advertising, the Act against Unfair Competition (UWG) allows pharmaceutical companies to bring legal action or seek an interim injunction against their competitors. Since the HWG deals with such cases, it directly deals with issues relevant to the application of competition law to the pharmaceutical sector.

Furthermore, the AMG and the German Act on Medical Devices (MPG) are also directly relevant, since the HWG refers to certain sections of the AMG and – to a lesser extent – the MPG. For example, with respect to the AMG, reference is made to the definition of pharmaceutical products (section 2 AMG), the definition of medicinal products (section 3 MPG), the package inserts (sections 11 and 12 AMG), the summary of product characteristics (section 11a AMG), the supply of product samples to certain experts (section 47 paragraph 3 AMG) and the shipment of pharmaceutical products to Germany (section 73 AMG). Furthermore, the rules for labelling and package inserts (sections 10 to 12 AMG) also have an impact on competition law regarding the parallel trade of pharmaceutical products in the European Union.

Section 1 ARC prohibits (in line with article 101 TFEU) any restrictions of competition. Furthermore, sections 19 and 20 ARC (in common with article 102 TFEU) prohibit the abuse of a dominant position and, in addition to article 102 TFEU, certain discriminatory conduct. As far as the legal relationships between public health insurance funds and physicians, dentists, psychotherapists, pharmacies and other healthcare providers are concerned, section 69 (2) of SGB V provides that sections 1 ARC (prohibition of anticompetitive agreements and concerted practices) and 19, 20 ARC (prohibition of the abuse of market power) apply accordingly. Section 172a paragraph 1 (SGB V) provides that the statutory provisions on merger control apply to mergers of public health insurance providers.

Competition legislation and regulation

4 Which legislation sets out competition law?

For the most part, competition law in Germany consists of the ARC and the UWG. The central legal basis for the FCO's work is the ARC, which entered into force on 1 January 1958 and has been amended eight times since then. A further amendment of the ARC is scheduled to enter into force in the first half of 2017, entailing comprehensive changes to align the ARC with European law. This new amendment will lead to numerous changes, inter alia, in the areas of cartel proceedings and fines, damages claims and merger control:

- The legislative proposal section 81 paragraph 3a) now introduces the liability of parent companies, subsidies and their legal successors, terminating a practice of changing ownership with the purpose of avoiding administrative fines.
- Another key aspect of the ninth ARC amendment will be the implementation of Directive 2014/104/EU of the European Parliament and of the Council of 26 November 2014 on certain rules governing actions for damages under national law for infringements of the competition law provisions of the member states and of the European Union. The implementation of the regulation was due on 27 December 2016 so the German legislator failed to meet the deadline set in the directive. However, once the ninth amendment enters into force the revision of the provisions related to damages actions will lead to significant changes in this area of law and undertakings involved in cartel infringements may even be more exposed to damages claims then they are already today.
- Further, as regards merger control law, the legislative proposal section 35 paragraph 1a) ARC contains a new criterion introducing a new and alternative €400 million transaction value threshold– an amendment that may likely also become relevant to future pharmaceutical transactions, especially with regard to patents, and the assessment of merger control filing obligations.

While the ARC contains antitrust regulations, the control of mergers and rules on the abuse of a dominant position, the UWG covers unfair trade practices, such as misleading statements and advertising or purposefully preventing competition. In addition to the UWG, the aforementioned HWG specifically regulates advertising in the healthcare sector. Nevertheless, the UWG still applies.

Besides the ARC, articles 101 and 102 TFEU apply fully in Germany, if trade between member states of the European Union is affected. These provisions are regularly applied by the FCO and German courts.

The FCO publishes guidelines and information leaflets regarding merger control, antitrust and public procurement issues on its website, but none of them are aimed specifically at the pharmaceutical industry. Nevertheless, some of them are directly relevant for the application of competition law in the pharmaceutical sector:

- Notice No. 9/2006 on the immunity from and reduction of fines in cartel cases of 7 March 2007;
- Revised Guidelines on the setting of fines in cartel administrative offence proceedings of 25 June 2013;
- Information leaflet on the settlement procedure used by the FCO in fine proceedings of February 2016;
- Notice No.18/2007 of the FCO on the non-prosecution of cooperation agreements of minor importance of 13 March 2007; and
- Guidance on substantive merger control of 29 March 2012.

In addition, the guidelines of the European Commission are applied both for the application of articles 101 and 102 TFEU and for the application of sections 1 and 2 ARC.

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

The FCO is the competent authority for investigating and deciding upon mergers in Germany. Since there are no industry-specific

competition authorities for merger control, the FCO is also responsible for any mergers in the pharmaceutical sector. Depending on the parties' respective turnover, either the European Commission or the FCO has the jurisdiction to review merger control cases.

The FCO is equally responsible for investigating anticompetitive agreements and abuses of dominant position. Apart from German competition law, the FCO also applies European competition law in cases where the European Commission is not competent under the Merger Control Regulation or, as far as articles 101 and 102 TFEU are concerned, under Regulation 1/2003. With respect to cases concerning anticompetitive conduct and abuse of a dominant position pursuant to articles 101 and 102 TFEU, cases are allocated to the competition authority that is best placed to handle the case. For this purpose, the European Commission and the FCO generally stay in close contact.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

Pursuant to section 81 paragraph 4 ARC, the FCO has the power to impose fines on companies responsible for violations of antitrust law of up to 10 per cent of the worldwide turnover of the preceding business year. Fines are calculated according to the guidelines on the setting of fines in cartel administrative offence proceedings (see question 4). In addition, the FCO may impose fines on individuals of up to €1 million for wilful participation in a cartel. In cases of negligent infringements of competition law, the maximum fine is €500,000.

Furthermore, the FCO may issue orders to stop certain conduct (cease-and-desist orders) and make declaratory decisions on past events (section 32 ARC). In cases of urgency, the FCO may even issue interim measures according to section 32a ARC, if there is a risk of serious and irreparable damage to competition.

Over the past years, there have been several decisions and investigations (one of them resulting in fines) related to the healthcare sector issued by the FCO.

In 2012, the FCO decided that a concerted offer by several associations of ophthalmologists regarding a tender of the public health insurance fund AOK Bavaria had violated competition rules. According to German law, however, the Bavarian Association of Health Insurance Doctors (KVB) may lawfully submit such a concerted offer with regard to the type of tender in question. In the case at hand, the persons had not acted as representatives for their individual ophthalmologists' association, but rather in their capacity as compulsory members of the KVB. As German law does not prohibit this kind of concerted practice, the FCO decided to terminate proceedings.

In 2013, the FCO imposed fines amounting to €6.5 million on WALA Heilmittel GmbH, and representatives of the company, for vertical price-fixing practices. According to the FCO, the company put pressure on retailers for years, obliging them to comply with WALA's recommended prices for its natural cosmetics products sold under the brand name 'Dr Hauschka'.

In September 2014, the FCO concluded its antitrust proceeding against a regional pharmacists' association. The association had an exclusivity agreement with major health insurance funds that patients ought to be supplied with blood glucose strips, preferably via pharmacies that operated in the area of activity of the respective association. This conduct restricted the sales possibilities of competitors, such as direct mailing companies or medical supplies shops. The association has promised to forgo its rights under its prohibitive control and influence clause.

On 14 September 2016, the FCO raided eight wholesalers of pharmaceutical products (Phoenix, Gehe, Sanacorp, AEP, Pharma Privat, Alliance, Noweda, Hageda-Stumpf) who are suspected to have concluded agreements with competitors violating antitrust laws, especially customer protection agreements, to divide markets and customers.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Prior to 2005, customers of companies that infringed antitrust law faced huge difficulties when suing for damages caused by cartels, with the result that such actions essentially played no significant role. However, since the 2005 amendment of the ARC, which implemented revisions as required by Regulation 1/2003, section 33, paragraph 3 ARC now provides a special legal basis for claims for companies and private persons suffering damages due to antitrust law infringements. According to section 33 paragraph 4 ARC, effective decisions of the FCO, the European Commission and of any national antitrust authority in the European Union are binding for civil courts in Germany with regard to the infringement. Furthermore, according to the decision of the BGH, the defendant carries the burden of proof to invoke the 'passing-on defence' (decision of 26 February 2013, Ref KRB 20/12). The ARC contains a rule on the statute of limitation for private antitrust claims under which the statute of limitation is suspended for the time the FCO, the European Commission or any national antitrust authorities of member states of the European Union initiate antitrust proceedings. Finally, the court may estimate the damages occurred to the claimant pursuant to section 287 of the Code of Civil Procedure.

These reforms, with regard to private antitrust litigation, have significantly increased the number of damages claims brought against companies violating antitrust laws in Germany and have already led to a number of judgments granting compensation. Currently, Germany is considered one of the most popular fora in the European Union, in which victims of competition law infringements bring follow-on actions regarding Commission infringement decisions. It remains to be seen whether Directive 2014/104/EU on antitrust damages actions will make it easier for victims of antitrust infringements to effectively obtain compensation for harm caused by antitrust violations before German courts. The Directive has not yet been implemented into German law by the ninth amendment of the ARC (for further information see question 4). Although at the present point in time there is no case practice with regard to damage claims in the pharmaceutical industry, such claims are expected in the future.

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

As stipulated in section 32e ARC, the FCO may conduct sector-wide inquiries if it suspects on the basis of fixed prices or other circumstances that any features of a market restrict or distort competition. While the FCO has carried out sector inquiries into a number of different industry sectors so far, these powers have not been exercised with regard to the pharmaceutical sector. As the European Commission conducts a sector inquiry into the pharmaceutical industry on a yearly basis, there is – in the opinion of the FCO – no need to perform the same work in Germany. Rather, the FCO relies on the results of the Commission's sector inquiry in this field.

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

Section 33, paragraph 2 ARC provides a privileged legal basis for compensation claims for associations with legal capacity for the promotion of commercial or independent professional interests, provided:

- they have a significant number of member undertakings selling goods or services of a similar or related type on the same market;
- they are able, particularly with regard to their human, material and financial resources, to actually exercise their statutory functions of pursuing commercial or independent professional interests; and
- the infringement affects the interests of their members.

In addition, section 54 ARC allows for a privileged status of consumer associations in antitrust proceedings. Consumer associations may join proceedings as an interested third party if the FCO's decision has effects on numerous consumers and where the interests of consumers in general are substantially affected.

Review of mergers

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

Sector-specific features are as relevant for the economic analysis of a merger in the pharmaceutical sector as in any other industry. In the pharmaceutical industry, the anatomical therapeutic chemical (ATC) classification developed by the European Pharmaceutical Market Research Association (EphMRA) is taken into account in German

merger control. However, there are no special rules applicable to mergers in the pharmaceutical industry. Thus, the general merger rules apply.

However, pursuant to section 42 ARC, German merger-control legislation provides for special proceedings that allow a merger previously prohibited by the FCO to be cleared by the Ministry for Economic Affairs. Such 'ministerial authorisation' is typically based on industrial policy reasons. During the past 10 years, section 42 ARC has been applied only twice. First, in a case from the public health sector in 2008, when the Ministry for Economic Affairs granted approval to a merger between two hospitals (Greifswald University Hospital and Wolgast Hospital), which was initially prohibited by the FCO. Second, only recently, in January 2016, a ministerial authorisation was granted to a merger between two food retailers (EDEKA and Tengelmann). In order to invoke a ministerial authorisation after a prohibited concentration, it must be proven that any restraints on competition are outweighed by advantages to the economy as a whole following from the concentration, or that the concentration is justified by an overriding public interest. As it is very difficult to provide evidence that one of these conditions is met, ministerial authorisations are and should only be applied in very exceptional cases.

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

Like the European Commission, the FCO includes in the relevant product market those products and services that are regarded as interchangeable or substitutable from the consumer's perspective by reason of the products' characteristics, their prices and their intended use. With respect to the pharmaceutical sector, the product market delineation under German merger control closely follows the approach of the European Commission (see B 3-11/03, *Novartis/Roche* as one of the rare examples of German case law in the pharmaceutical sector).

Accordingly, the European Commission has taken as a starting point the ATC division of medicines by therapeutic use devised by EphMRA and maintained by EphMRA, as well as the Intercontinental Medical Statistics. The ATC classification is hierarchical and has 16 main categories (A, B, C, D, etc), each with different levels. Furthermore, the FCO – as confirmed by the Higher Regional Court of Düsseldorf – differentiates between the product market of wholesale trading with a full range of pharmaceuticals on the one hand (full-line), and direct sales from producers (direct-line) or distributors with only a limited range of products (short-line) on the other hand (FCO, WuW/E BKartA 1747 – *Anzag/Holdermann*).

Regarding pharmaceuticals available without prescription (over-the-counter (OTC)) products, the European Commission has defined a separate product market between OTC and prescription pharmaceuticals. It considers this separation as appropriate since the legal framework for marketing and distribution tends to differ between the two categories of medicines. Like the European Commission, the FCO makes no distinction between generics and originator drugs.

The relevant geographic market for pharmaceutical products including OTC products is national in scope. Regarding wholesale distribution of pharmaceuticals, the relevant geographic market is regional in scope. On average, the wholesaler supplies pharmaceutical goods to the pharmacies three times a day. Therefore, the geographical market is limited to a radius of approximately 200km (this may vary, depending on regional distinctions and frequency of supply) (OLG Düsseldorf – *Sanacorp/ANZAG*).

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

The German FCO applies the European Commission's guidance on research and development. Thus, the efficiency-based arguments of the Commission Regulation (EU) No. 1217/2010 of 14 December 2010, on the application of article 101(3) of the TFEU to certain categories of research and development agreements (OJ L 335/36 of 18 December 2010) (in the following: 'R&D Block Exemption'), are applied. Under the European Commission's R&D Block Exemption, joint research and development between competing undertakings is exempted from the ban on cartels under certain conditions, provided that the combined market share of the parties to a research and development agreement does not exceed 25 per cent on the relevant product and technology markets.

Local and regional arguments, however, are not considered in this context.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

In its Guidelines on market dominance in merger control, the FCO considers a horizontal merger of companies active on the same product and geographic market to raise competition concerns if it would significantly impede effective competition, and, in particular, create or strengthen single firm dominance or collective dominance (section 36 paragraph 1 ARC). In this respect, according to section 18, paragraph 4 ARC, a holder of market shares of at least 40 per cent is presumed to hold a single dominant position. If three or fewer undertakings have a joint market share of 50 per cent, or five or fewer undertakings accumulate a joint market share of two-thirds, a joint dominant position is legally presumed (section 18, paragraph 3, sentence 6, Nos. 1, 2). Furthermore, the Higher Regional Court of Düsseldorf, which is competent to review the FCO's merger control decisions, has found that a strengthening of an already established dominant position does not even need to be significant to justify a prohibition of a merger.

According to the European Commission case law in the pharmaceutical sector, a concentration is unlikely to significantly impede effective competition in that sector if the parties with overlapping activities have combined market shares below 35 per cent, as long as several competitors remain and they include either market leaders or companies with a strong market position (Comp/M.4198, Bayer/Schering). Hence, extensive market investigations have been focused particularly on cases in which the parties achieved a combined share of over 35 per cent and the increment in the share was over 1 per cent (eg, COMP/M 6705, *Procter & Gamble/Teva Pharmaceuticals* OTC II). In the absence of German case law, this is indicative of the likely approach but, in practice, this may differ from case to case.

As the European Commission can also intervene in concentrations where products are still in the developing phase (see question 17), it is equally necessary to consider not only actual but also potential competition when analysing the relevant markets. In this respect, the most important criteria are barriers to entry into the market.

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

Because of a lack of German case law with respect to the assessment of 'pipeline products' (ie, products that are not yet on the market but that are at an advanced stage of development, normally after large sums of money have been invested), it can only be assumed that the FCO will follow the European Commission's approach, as outlined in the 2004 Guidelines on the assessment of horizontal mergers. Accordingly, as effective competition may be significantly impeded by a merger between two significant innovators, even potential pipeline products must be taken into account when assessing the competitive situation in the pharmaceutical industry. The European Commission considers that a pipeline product is at a sufficiently advanced stage of development to be considered a possible competitive constraint when it reaches clinical trials (Phase III). At this stage, the overlap of pipeline products follows the same rules that apply for the overlap of other products. In cases where the aggregate market share of the parties involved exceeds 35 per cent (see question 16) and market launch is expected to take place within two years, the European Commission will examine the effects of overlapping pipeline products very carefully.

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

According to section 40, paragraph 3 ARC, the clearance of a merger may be granted subject to conditions or obligations where these do not seek to subject the undertakings concerned to ongoing controls. Generally speaking, the conditions and obligations imposed should either aim to prevent the establishment or strengthening of a dominant position, or to improve the prevailing conditions of competition. The FCO has a clear preference for structural remedies over behavioural

commitments, as behavioural remedies are often not considered to be sufficient to address competition concerns.

The wording of section 40, paragraph 3 ARC grants the FCO a wide margin of discretion and thus, a full range of remedies may be imposed. Commitments may include the sale of given business division, the obligation to divest a certain product line, licences and patent portfolios, or other measures capable of promoting effective competition.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

In general, according to section 37, paragraph 1, no. 1 ARC, the acquisition of a substantial asset of an undertaking triggers merger control notification requirements if the turnover to be allocated to the assets that are being acquired meets the second domestic turnover threshold (€5 million), provided that the other relevant turnover thresholds are fulfilled by the buyer. The definition of 'substantial asset' is wide in scope and includes monetary benefits, which are capable of influencing the purchaser's market position. Such benefits may include the purchase of an outstanding patent portfolio or licences that generate turnover in a market. Thus, the acquisition of patents is generally subject to merger control if existing turnover may be allocated to the patents. Consequently, the acquisition of patents that already generate turnover may be subject to German merger control while the acquisition of patents to which no turnover may be allocated may not qualify for merger control. Provided that the licence or patent is classified as a substantial asset with a turnover-generating activity exceeding the second domestic turnover threshold and provided that its acquisition can be considered as an external increase of market shares (the purchaser obtains the vendor's market position), such acquisition would be subject to merger control (BGH WuW/ DE-R 1979, 1981 – *National Geographic I*).

If, once the ninth amendment of the ARC is implemented, as is currently suggested in the draft bill, (see question 4), the new €400 million transaction value threshold may additionally trigger filing obligations if that threshold is met and the assets to be acquired have a sufficient domestic nexus (eg, patents or licences also cover Germany).

Anticompetitive agreements

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

The general framework for assessing anticompetitive agreements is stipulated in section 1 ARC and article 101 TFEU (see question 4). All agreements between undertakings, decisions by associations of undertakings or concerted practices that clearly restrict competition by object, such as price fixing, market or customer allocation, bid rigging or restrictions of supply, are per se considered to be illegal, since they have by their very nature a high potential to result in negative effects on competition. If an agreement does not restrict competition by object, it must be examined whether it has appreciable restrictive effects on competition in a given market. If an agreement or practice has the object to restrict competition, it is, however, not necessary to examine any actual or potential effects.

Where an agreement or practice gives rise to restrictive effects on competition, one has to consider possible reasonable justifications or gained efficiencies that outweigh the negative competitive effects in the light of article 101 (3) TFEU and section 2 ARC, respectively. In this respect, it is for the undertaking concerned to prove that the agreement or practice can be legally exempted. Thereby, one may consider the respective European Block Exemption Regulations and guidelines with regard to vertical restraints adopted by the European Commission, which are directly applicable in German antitrust law according to section 2, paragraph 2 ARC.

18 To what extent are technology licensing agreements considered anticompetitive?

As there is no specific German legislation on technology licences, the Commission Regulation No. 316/2014 on categories of technology transfer agreements and the accompanying Guidelines apply accordingly. According to the European Commission, the licensing of technology rights are generally considered to improve economic efficiency and be pro-competitive as technology transfer can reduce duplication of R&D, spur incremental innovation, facilitate diffusion and generate product market competition.

In order to fall within the scope of this block exemption regulation, the respective technology transfer agreement may not contain any 'hard-core' restrictions, including resale price maintenance, limits on production, or exclusive allocation of customers and markets. In addition, as a second criterion, the agreement has to fall under the 'safe harbour' rule. This criterion is satisfied where the aggregate market share of two competing undertakings does not exceed the threshold of 20 per cent (for non-competitors the threshold is 30 per cent). For further details, please refer to the chapter on EU competition law.

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

Commercialisation agreements such as co-promotion and co-marketing agreements can generate significant efficiencies, stemming from economies of scale or scope, especially for smaller producers. Yet, commercialisation agreements can also lead to restrictions of competition, such as price fixing, output limitation, market and customer sharing, particularly when they are entered into by competitors with a considerable degree of market power. In this respect, the European Commission's Notice on the applicability of article 101 TFEU to horizontal cooperation agreements is considered by the FCO to provide useful guidance, in order to assess the potential anticompetitive effects of cooperation between competing undertakings.

According to the decision of the European Commission in *Johnson & Johnson and Novartis*, there is considerable risk of antitrust violations if close competitors enter into a co-promotion agreement in order to delay the market entry of a cheaper generic medicine.

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

Typical horizontal restraints of competition include price fixing between competing undertakings, restricting supply by output limitation, allocation of markets or customers and exchange of commercially sensitive information. Such hard-core restrictions of competition are per se considered to be unlawful. Where there is an explicit or mutual consent between the competitors to hinder, prevent or distort competition on a given market, appropriate confidentiality provisions cannot resolve the illegality of the anticompetitive conduct.

Other forms of cooperation between competing undertakings, however, such as R&D agreements, technology transfer agreements or production joint ventures, are subject to an effects-based analysis by the European Commission. With regard to these agreements, establishing a 'Chinese Wall' can be considered necessary in order to ensure that the parties do not exchange more information than is actually required for a sustainable and successful venture.

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

From a competition point of view, vertical agreements are typically problematic where they contain exclusivity clauses, clauses restricting the purchaser in setting his or her resale prices or the protection of certain sale areas. When assessing potential competition concerns relating to vertical agreements, the block exemption regulation on vertical agreements and the corresponding Guidelines on vertical agreements are directly applicable pursuant to section 2, paragraph 2 ARC. Vertical agreements may be covered by the block exemption regulation, and thus be exempted from the prohibition of article 101(1) TFEU, provided that:

- the agreement does not contain any hard-core restrictions;
- the duration of a direct or indirect non-compete obligation does not exceed five years; and
- both the supplier and the buyer of the goods or services do not have a market share exceeding 30 per cent on the relevant markets.

In 2013, the FCO fined WALA Heilmittel GmbH and its representatives €6.5 million for vertical price-fixing practices. The company was accused of having put pressure on retailers for years, obliging them to comply with WALA's recommended prices for its natural cosmetics products sold under the brand name 'Dr Hauschka'.

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

As German courts have not yet dealt with any 'pay-for-delay' cases, it is very likely that the courts would seek guidance from cases stemming from the European courts and the European Commission. The European Commission has taken a firm stance recently, particularly in the case of settlement agreements between originator companies and generics manufacturers. In 2013 and 2014, it imposed high fines in three proceedings against, among others, Lundbeck, Johnson & Johnson and Novartis, and Servier, as well as other producers of generic medicines:

- On 19 June 2013, the European Commission imposed a fine of €93.8 million on Danish pharmaceutical company Lundbeck and fines of €52.2 million on several producers of generic medicines (Case COMP/AT. 39226 – *Lundbeck*). The General Court upheld the Commission's *Lundbeck* decision (cases T-472/13, T-460/13, T-467/13, T-469/13, T-470/13, T-471/13) and ruled for the first time that pharma pay-for-delay agreements breach EU antitrust rules. In particular, it found that the Commission was correct in finding that, irrespective of any patent dispute, generics competitors agreed with Lundbeck to stay out of the market in return for value transfers and other inducements, which constituted a buying-off of competition. Additionally, the Commission had correctly established that the agreements eliminated the competitive pressure from the generic companies and are a restriction of competition by object. Furthermore, Lundbeck was not able to justify why these particular agreements would have been needed to protect its intellectual property rights.
- In December 2013 the Commission fined the US pharmaceutical company Johnson & Johnson and Novartis of Switzerland for the conclusion of an anticompetitive agreement to delay the market entry of a cheaper generic version of the pain-killer fentanyl in the Netherlands, thereby infringing article 101 TFEU (Case COMP/AT 39685 – *Fentanyl*). The *Fentanyl* decision was not appealed.
- On 9 July 2014, the Commission imposed fines in the amount of €427.7 million on the French pharmaceutical company Servier (Case COMP/AT 39612 – *Perindopril*) and five producers of generic medicines for concluding a series of deals all aimed at protecting Servier's product perindopril, from price competition by generics in the EU. Through a technology acquisition and a series of patent settlements with generic rivals, Servier implemented a strategy to exclude competitors and delay the entry of cheaper generic medicines to the detriment of public budgets and patients in violation of article 101 TFEU and article 102 TFEU. The *Servier* Decision has been appealed by Servier SAS (Suresnes, France), Servier Laboratories Ltd (Wexham, UK) and Les Laboratoires Servier SAS (Suresnes) on 21 September 2014 in case T-691/14 and is pending before the Court.

In addition, an ex officio investigation to assess an alleged pay-for-delay agreement between Cephalon and Teva is still ongoing.

As underlined again in the seventh Report on the Monitoring of Patent Settlements, which was published by the European Commission in December 2016, a particular risk of potential antitrust violations originates from category B II settlements (ie, settlements that restrict generic entry and show a value transfer from the originator to the generic company and that might therefore attract competition law scrutiny). Accordingly, a patent settlement may entail an infringement of antitrust rules if the respective agreement has the object or effect of restricting competition.

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

Certain procurement practices of German healthcare funds, for example, 'open house agreements', significantly increase transparency in the industry. As public healthcare funds, as the major part of the demand, are exempted from the application of the ban on cartels by statutory law, the risk deriving from this market transparency with regard to potential violations of antitrust law burdens solely the supplier of pharmaceuticals.

Anticompetitive unilateral conduct

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

According to section 19, paragraph 1 ARC, the abusive exploitation of a dominant position by one or several undertakings is prohibited. Pursuant to section 19, paragraph 2 ARC, an abuse exists, if a dominant undertaking, as a supplier or purchaser of certain kinds of goods or commercial services:

- impairs the ability of other undertakings to compete in a manner affecting competition in the market without any objective justification;
- demands payment or other business terms that differ from those that would very likely arise if effective competition existed;
- demands less favourable payment or other business terms than the dominant undertaking itself demands from similar purchasers in comparable markets, unless there is an objective justification for such differentiation;
- refuses to allow another undertaking access to its own networks or other infrastructure facilities against adequate remuneration, provided that without such concurrent use, the other undertaking is unable for legal or factual reasons to operate as a competitor of the dominant undertaking on the upstream or downstream market; or
- uses its market position to invite or to cause other undertakings in business activities to grant them advantages without any objective justification.

In addition, pursuant to section 20, paragraph 3 ARC, undertakings with superior market power in relation to small and medium-sized competitors shall not use their market position directly or indirectly to hinder such competitors in an unfair manner.

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

Section 18 ARC provides for certain legal assumptions of dominance. Generally speaking, an undertaking is considered dominant on the relevant product and geographic market where it has no competitors, it is not exposed to any substantial competition, or it has a predominant market position in relation to its competitors.

In this respect, according to section 18, paragraph 4 ARC, an undertaking is presumed to be dominant if it has a market share of at least 40 per cent. In addition to the market share of the party in question, the FCO carefully assesses – as outlined in a non-exhaustive list in section 18, paragraph 3 ARC – the competitive structure on the given market by taking into account, among other things, any existing legal entry barriers, any actual or potential competition from other undertakings, the financial resources of the party and links with other companies.

Pursuant to section 18, paragraph 6, a number of undertakings are presumed to be dominant if three or fewer undertakings have a common market share of 50 per cent, or where five or fewer undertakings accumulate a joint market share of 66.6 per cent. Where undertakings find themselves in a situation covered by one of these two assumptions of collective dominance, the undertakings carry the burden of proof that they are actually not part of a dominant oligopoly.

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

Provided that the patent either forms a distinct product market or that there are only a very limited number of competing substitutes or technical solutions available for the technology covered by the patent, the patent itself entails a considerable degree of market power. As a consequence, the mere ownership of a patent may be considered evidence of dominance, simply on account of a single patent being held. If, however, there are other substitute technologies competing with the patent, it is less likely that the patent holder will have a sufficient degree of market power to be considered dominant in the respective market.

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

The application for the grant of a patent may lead to the creation or the strengthening of a dominant position of the patent applicant on a

relevant product and geographic market. Yet, the mere application for a patent for a new medicinal product is not very likely to infringe antitrust law.

If, however, the application for a patent is based on a horizontal agreement between competitors with the intention of establishing a market allocation by allocating distinct patents, competition authorities may consider the agreement as a 'restriction of competition by object', and thus as a violation of the competition rules within the meaning of article 101(1) TFEU and section 1 ARC, respectively. Further, as demonstrated in the *ITT Promedia* judgment of the Court of First Instance (Case T-111/96), the attempt of a dominant originator company to prolong the duration of a patent by engaging in vexatious litigation can equally be considered as a violation of competition law rules. Likewise, applying for a patent with the sole purpose to prevent a competitor from developing the subject matter of that patent may be considered as a restriction of competition by object (eg, when such a strategy mainly focuses on excluding competitors without pursuing innovative efforts).

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

Generally speaking, life-cycle management strategies are unlikely to be considered a breach of the antitrust rules. Yet, certain strategic actions of the dominant patent holder – for instance, interventions before national regulatory authorities, which are clearly aimed to protect actual or potential competition – are met with much scepticism (a potential article 102 TFEU case) because of foreclosure effects. Competition authorities may consider these kinds of defensive patenting strategies aimed to protect actual or potential competition as unlawful, particularly if they have little or no prospects of being developed or commercialised. Hence, when applying life-cycle management strategies, the dominant company has to forward objective justifications other than the intention to delay or even prevent the introduction of generic products.

Additionally, where life-cycle management strategies are coordinated directly or indirectly with competitors, such conduct has as its object the restriction of competition. Thus, such patenting strategies are considered to be a clear-cut violation of the antitrust rules in the light of article 101(1) TFEU and section 1 ARC respectively, as they can lead to the allocation of markets and customers.

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

The practice of patent holders launching their own generics shortly before the expiry of the protection of a certain patent with the intention of allowing an 'early entry' has been common practice in the pharmaceutical market. Even though possible generic producers would face more competition, the European Commission has considered early market launches of generic substitute by the originator company to be pro-competitive, since consumers have at an early stage an alternative source of supply on the expiry of the patent. In Germany, however, there is not yet any national case law available concerning the practice of authorised generics.

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

The pharmaceutical sector provides for fixed retail prices of pharmaceutical products subject to prescriptions. Thus, the general antitrust legislation with regard to retail price fixing does not apply to prescribed pharmaceutical products.

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

There has not been a notable general increase in antitrust enforcement in the pharmaceutical sector in Germany. Unlike the European Commission, the FCO has not yet issued fines with regard to late life-cycle management behaviour of pharmaceutical companies. Rather, the FCO has been concentrating on vertical restriction of antitrust law in the pharmaceutical sector in recent years, as demonstrated by its decision practice with regard to resale price maintenance of pharmaceutical OTC products. The latest fines decision was rendered against WALA Heilmittel GmbH for vertical price-fixing practices in 2013, when the FCO imposed fines amounting to €6.5 million.

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The legislative framework for the marketing, authorisation and pricing of pharmaceutical products in India (including generic drugs) consists of:

- the Drugs and Cosmetics Act 1940 (the Drugs and Cosmetics Act), the Drugs and Cosmetics (Rules) 1945 (the Drugs and Cosmetics Rules), and the Drugs (Control) Act 1950, which regulate the manufacture and distribution of pharmaceutical products in India;
- the Drugs (Price Control) Order 2013 (the Drugs Price Control Order), framed under the Essential Commodities Act 1955 (the Essential Commodities Act), which regulates the pricing of certain essential medicines listed therein;
- the Medicinal and Toilet Preparations Act 1955, which levies an excise duty on medicinal preparations that contain alcohol, narcotic drugs or narcotics; and
- the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954, which controls the advertisement of drugs in India.

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

The legislative framework for the distribution of pharmaceutical products consists of:

- the Drugs and Cosmetics Act 1940, which regulates the import, manufacture, distribution and sale of drugs in India; and
- the Narcotic Drugs and Psychotropic Substances Act 1985, which regulates the purposes for, quantity, and price at which certain drugs may be sold.

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

Competition laws in India are to be read in conjunction with other applicable laws. Therefore, the legislation governing the marketing, authorisation and pricing of pharmaceutical products must be read in conjunction with competition laws in India.

More specifically, there are two aspects of the regulatory framework listed in question 1 that are most relevant to the application of competition law in the pharmaceutical sector:

- the Drugs Price Control Order, which empowers the government of India to set ceiling prices for certain scheduled formulations on the basis of which manufacturers may set maximum retail prices, after accounting for local taxes. For new drugs, manufacturers may set maximum retail prices on the basis of retail prices determined by the government and local taxes; and
- the Essential Commodities Act, which empowers the government to regulate the production, supply and distribution of essential commodities, including pharmaceutical products.

Competition legislation and regulation

4 Which legislation sets out competition law?

The Competition Act 2002 (CA02) and its allied regulations constitute the framework for competition law in India. These laws are primarily enforced by the Competition Commission of India (CCI).

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

The CCI has the responsibility to investigate and decide on mergers and the anticompetitive effect of conduct and agreements in the pharmaceutical sector, together with the Director General for Competition (ie, the investigative arm of the CCI). An appeal from the decision of the CCI lies to the Competition Appellate Tribunal (COMPAT). A further appeal lies to the Supreme Court of India.

Under the government's foreign direct investment policy, there can be up to 100 per cent foreign direct investment in brownfield and greenfield ventures in the pharmaceutical industry. However, investment in brownfield ventures is subject to the approval of the Foreign Investment Promotion Board.

The restructuring or amalgamation of pharmaceutical companies needs prior approval from the high court of the state in which the registered office of the company is located. Moreover, the acquisition of shares in a publicly listed pharmaceutical company could also trigger the requirement for prior approval from the Securities and Exchange Board of India.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

The monetary penalty for anticompetitive conduct can extend up to 10 per cent of a company's average turnover for the preceding three financial years. In the case of cartels, the fine can be up to three times the profit made during the cartel period. The CCI may also impose fines on individuals responsible for anticompetitive conduct.

For instance, in *M/s Arora Medical Hall, Ferozepur v Chemists & Druggists Association*, Ferozepur, the CCI imposed a penalty of an amount equal to 10 per cent of the average income of the three preceding years on individual office bearers of the Chemists and Druggists Association, Ferozepur, for entering into an agreement to limit supply of drugs and medicines. This set a trend, and the CCI has adopted similarly stringent approaches in subsequent cases, such as *Rohit Medical Stores v Macleods Pharmaceutical Limited and Ors* (Case No. 78 of 2012), where the CCI imposed a penalty of equal to 10 per cent of the average income of the three preceding years on an office bearer of the Himachal Pradesh Society of Chemists and Druggists Alliance (HPSCDA) for his active involvement in anticompetitive practices carried out by the HPSCDA.

The CCI went a step further in *PK Krishnan v Alkem Laboratories Limited and Ors*, and imposed a heavy penalty of 10 per cent of the average turnover of the Chemists and Druggists Association of Goa (CDAG) for not complying with previous orders of the CCI, wherein it had ordered the CDAG to cease and desist from certain anticompetitive practices.

The CCI is also empowered to modify anticompetitive agreements (whether horizontal, vertical or agreements entered into by a dominant enterprise), order the division of a dominant enterprise, or pass any other order it may deem fit.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

COMPAT may pass an order for recovery of compensation from any enterprise for any loss or damage that is shown to have been suffered as a result of any contravention of the provisions of Chapter II of the CA02 (anticompetitive agreements, abuse of dominant position and merger control). This claim for compensation can be filed by the central government, a state government, local authority, or any enterprise or person.

The claim may arise from the findings of the CCI, or an order of COMPAT (in an appeal against the findings of the CCI). Compensation could also be sought for contravention of orders of the CCI or COMPAT. In the recent decision (not in the pharmaceutical sector) of *Adidas India Marketing v Nike India & Ors*, COMPAT held that the power of the CCI to award compensation is restricted to cases where loss or damage has been caused as a result of monopolistic or restrictive or unfair trade practice, and the CCI has no jurisdiction where damage is claimed for a mere breach of contract. In this case, COMPAT also imposed a fine on the applicant for filing a frivolous compensation claim.

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

The CCI is empowered to conduct sector-wide inquiries to determine whether industry practices contravene the CA02. The inquiry may be suo moto, on the basis of a complaint or on a reference by the government.

In July 2010, the CCI commissioned a study titled 'Competition Law and Indian Pharmaceutical Industry'. The study, conducted by the Centre for Trade and Development, New Delhi, concluded that although there was exponential growth in the industry, there was limited price competition among retailers.

In 2013, the CCI initiated another study on the domestic pharmaceutical industry to look into issues relating to the patents regime, pricing, the process of manufacture, and the terms and conditions of sale of drugs through chemists and druggists in India. The outcome of the study is still awaited.

Further, in 2015, the CCI invited entities to carry out a study on the pharmaceutical and healthcare industry in India, to look into public and private hospitals, insurance companies, pharmaceutical firms and their associations, doctors and their associations, to understand if there were any anticompetitive practices prevalent in these industries. We are still waiting for the outcome of the study.

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

Non-government groups can play a role in the application of competition laws in two ways: they may give information to the CCI regarding anticompetitive conduct, on the basis of which an investigation may be initiated, and they may be asked for their views as third parties during an ongoing investigation. There have been instances of investigations being initiated by the CCI on the basis of information provided by trade or consumer associations.

Review of mergers

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

When reviewing mergers, the CCI is required to take into account specific features of the sector in question. The CA02 sets out certain factors that must be considered by the CCI, such as the existence of barriers to entry, degree of countervailing power, actual and potential levels of competition, and nature and extent of innovation, all with reference to the 'relevant market'.

The CCI's recognition of sector-specific qualities is also apparent in its assessment of ancillary restraints. For example, in *Orchid/Hospira* (2012), the parties argued that the non-compete clause restricting research, development and testing by the seller and its promoters was standard industry practice. While the CCI reduced the duration of the non-compete clause from eight to four years, its scope was expanded to allow the seller to conduct research, development and testing on such new molecules that are currently not in existence.

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

The CCI has reviewed several pharmaceutical mergers, and geographic markets are usually national in scope. However, its decisions do not shed much light on the preferred methodology to define relevant product markets in this sector. It was only in *Mylan Inc/Agila Specialities Private Limited* (2013), that the CCI first made limited reference to therapeutic categories, intended use and characteristics of the product.

Thereafter, differing approaches have been adopted, possibly based on the complexity of the case. In *New Moon BV* (2014) the CCI considered the relevant molecular level of the drugs when analysing overlaps. This approach was replicated in *Sun Pharmaceutical Industries Limited/Ranbaxy Laboratories Limited* (referred to as the *Sun/Ranbaxy* decision), and the CCI went on to state that each generic brand of a given molecule is a chemical equivalent and therefore considered substitutable. However, *GlaxoSmithKline plc/Novartis AG* (2014) saw a return to market delineations on the basis of therapeutic category followed by a more granular, molecular-level approach in *Pfizer Inc/Hospira Inc* (2015).

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

The CA02 prescribes several factors that the CCI must take into account when determining if any conduct or agreements results in an appreciable adverse effect on competition (AAEC) in the market. These factors include anticompetitive harms such as:

- creation of barriers to new entrants in the market;
- driving existing competitors out of the market; and
- foreclosure of competition by hindering entry into the market.

There are also certain pro-competitive factors that the CCI must consider, specifically:

- accrual of benefits to consumers;
- improvements in production or distribution of goods or provision of services; or
- promotion of technical, scientific and economic development by means of production or distribution of goods or provision of services.

As such, in determining whether any conduct or agreement results in AAEC, the CCI must consider efficiency-based arguments put forth by the parties. Even in the case of mergers, research and development is an important assessment parameter, and parties would therefore be able to invoke efficiency-based arguments to address antitrust concerns.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

The CA02 and its allied regulations do not specify any thresholds for overlap that could automatically be considered problematic. The test is whether the overlap is likely to cause an AAEC in India.

Merging parties ordinarily notify the CCI in a simple Form I. However, when there is a horizontal overlap in excess of 15 per cent, or a vertical overlap over 25 per cent, the CCI (Procedure in Regard to the Transaction of Business relating to Combinations) Regulations 2011 (as amended up to 4 April 2013) recommend that parties notify the CCI using the more detailed Form II.

In the *Sun/Ranbaxy* decision, the CCI deemed those categories of overlapping products problematic where the combined market share of Sun Pharmaceutical Industries Limited and Ranbaxy Laboratories Limited was between 65 per cent and 95 per cent. This prompted the CCI to pass its very first remedies order to divest a number of products.

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

The overlap with respect to products that are being developed will be problematic if it is likely to cause an AAEC in India.

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

The CCI may approve, disapprove or propose modifications to notified mergers. In the pharmaceutical sector, the CCI has on two occasions modified the term of long-term non-compete clauses from their original duration down to four years.

Sun/Ranbaxy was the first case in which the CCI initiated and concluded a detailed Phase II investigation. In certain product segments, the CCI concluded that the transaction would result in market shares that were deemed likely to result in AAEC. Accordingly, the CCI ordered Sun and Ranbaxy to divest seven brands and appointed PricewaterhouseCoopers to supervise the divestment process. The purchase of the divested assets by Emcure Pharmaceuticals was approved by the CCI in March 2015.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

The CA02 makes it mandatory for merging enterprises that meet the prescribed asset or turnover thresholds to notify an acquisition of assets, shares or voting rights. The CA02 defines the term 'value of assets' to include the value of patents. The acquisition of a licence could also meet the merger reporting requirements, and in the past the grant of an exclusive licence has been equated to a transfer of assets.

Anticompetitive agreements

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

Under the CA02, any agreement in respect of production, supply, distribution, storage, acquisition or control of goods or provision of services, which causes or is likely to cause an AAEC within India shall be void. Specifically, horizontal agreements that fix prices, limit or control production or supply of goods or services, share markets or sources of production, or result in big rigging are presumed anticompetitive. The CA02 provides a carve-out for joint ventures that result in efficiencies in the production, supply, distribution, storage, acquisition or control of goods or the provision of services. Vertical restraints, including tie-in arrangements, refusal to deal, resale price maintenance arrangements, exclusive supply and exclusive distribution agreements, are prohibited only if they cause or are likely to cause an AAEC in India.

The aforementioned provisions relating to anticompetitive agreements do not apply to reasonable restrictions imposed for the protection of intellectual property rights and agreements exclusively relating to the export of goods or services.

The CA02 lists certain factors that the CCI must consider when establishing the anticompetitive effect of an agreement, including creation of barriers to entry, market foreclosure, removal of competitors, benefit to consumers, improvement in production or distribution of goods or services and promotion of technical, scientific and economic development in its assessment of anticompetitive agreements.

18 To what extent are technology licensing agreements considered anticompetitive?

Technology licensing agreements may be considered anticompetitive if they cause or are likely to cause an AAEC in India. The manner of assessment will vary depending on whether the agreement is horizontal or vertical in nature (see question 17).

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

Co-promotion and co-marketing agreements are considered anticompetitive if they directly or indirectly fix prices, limit or control the production or supply of goods or services, or share markets or sources of production (see question 17).

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

Agreements with actual or potential competitors are problematic if they directly or indirectly fix prices, limit or control the production or supply of goods or services, or share markets or sources of production. Implementing firewalls and appropriate confidentiality provisions could mitigate but not eradicate the risk of scrutiny by the CCI for potential anticompetitive conduct.

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

Vertical restraints are not per se anticompetitive, unless they cause or are likely to cause an AAEC in India. The CA02 lists certain vertical agreements such as tie-in arrangements, refusal to deal, resale price maintenance arrangements, exclusive supply and exclusive distribution agreements, which could be anticompetitive if they cause or are likely to cause an AAEC in India, but this list is not exhaustive.

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

Antitrust issues arising out of the settlement of patent disputes have yet to be considered by the CCI. However, the CA02 provides limited safe harbour from the provisions relating to anticompetitive agreements to reasonable restrictions imposed for the protection of intellectual property rights under the Patents Act 1970 (the Patents Act).

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

The current Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 prohibits any form of relationship between pharmaceutical enterprises and HCPs. However, in practice, the interaction between pharmaceutical companies, device manufacturers, or their agents and HCPs has always been opaque. It would be difficult to thus determine the likelihood of anticompetitive information exchanges between pharmaceutical companies and HCPs.

Recently, the government of India required all clinical trials to be compulsorily registered with the Clinical Trial Registry India. However it is unclear whether disclosure in relation to clinical trials would facilitate any information exchange between pharmaceutical companies. In addition to these regulations and rules, there are several other regulations that require pharmaceutical companies to disclose confidential information to third parties.

Such information exchange would not in itself constitute a contravention under the CA02. However, the CA02 does not contain any express exemption for conduct that is undertaken in compliance with any other regulation (other than the relevant exemption for intellectual property rights). Therefore, if the information exchange between pharmaceuticals companies mandated by other regulations results in any collusive conduct, the enterprises would still be liable under the provisions of the CA02.

Anticompetitive unilateral conduct

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

The CA02 lists certain conduct, which, if practised by a firm in a dominant position, shall be considered an abuse of dominant position. This includes:

- imposing unfair or discriminatory conditions or price on sale of goods;
- limiting or restricting production of goods, or technical or scientific development;
- denying market access;
- making the conclusion of contracts subject to the acceptance of obligations that have no connection with the subject matter of the contract; or
- using its dominant position in one relevant market to enter into or protect another.

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

A firm is considered dominant if it enjoys a position of strength that allows it to act independently of competitive forces in the market, or to affect the relevant market, competitors or consumers in its favour. The CA02 lists certain factors that the CCI must consider while assessing whether a firm is in a dominant position, including:

- market share of the enterprise;
- size and resources of the enterprise;
- size and importance of the competitors;
- economic power of the enterprise including commercial advantages over competitors;
- vertical integration of the enterprises or sale or service network of such enterprises;
- dependence of consumers on the enterprise;
- monopoly or dominant position whether acquired as a result of any statute or by virtue of being a government company or a public sector undertaking or otherwise;
- entry barriers including barriers such as regulatory barriers, financial risk, high capital cost of entry, marketing entry barriers, technical entry barriers, economies of scale, high cost of substitutable goods or service for consumers;
- countervailing buying power;
- market structure and size of market;
- social obligations and social costs;
- relative advantage, by way of the contribution to the economic development, by the enterprise enjoying a dominant position having or likely to have an AAEC; and
- any other factor the CCI may consider relevant for the inquiry.

The CA02 does not currently recognise the concept of joint dominance.

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

The assessment for dominance of a patent holder will be conducted in the manner set out in question 25. In the past, the CCI has found that the volume of patents held by a party could result in a finding of dominance (*Micromax Informatics Limited/Telefonaktiebolaget LM Ericsson* (case No. 50 of 2013)).

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

The CA02 does not prohibit the mere application for the grant of a patent. The patent holder could be exposed to liability only if it violates the provisions of the CA02.

As stated in response to question 22, the CA02 provides limited safe harbour to reasonable restrictions imposed for the protection of intellectual property rights granted under the Patents Act. However, enforcement of a patent could expose the patent holder to liability if the latter is found to be in a dominant position.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

Life-cycle management strategies in relation to patents have yet to be considered by the CCI. See question 27.

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

Authorised generics could be problematic under the provisions relating to vertical agreements (if the arrangements cause or are likely to cause an AAEC in India) and abuse of dominant position (for example, if the licensing arrangement were to result in the denial of market access).

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

The pharmaceutical industry is driven by innovation, and hence relies extensively on the protection derived from patents. For this reason, the CA02 provides limited safe harbour from the provisions on anticompetitive agreements to reasonable restrictions imposed for the protection of intellectual property rights under the Patents Act. However, this carve out does not extend to any conduct that would constitute an abuse of dominant position under the CA02.

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

Not applicable.

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The Pharmacists Ordinance (New Version), 5741-1981 (the Pharmacists Ordinance), regulates, among other things, the registration, standard of quality, marketing and manufacture of pharmaceuticals authorised by the Ministry of Health (MoH). The Institute for Standardization and Control of Pharmaceuticals, under the auspices of the MoH, is the primary agency charged with the implementation of the Pharmacists Ordinance. The general rule set by the Pharmacists Ordinance is that manufacturing, marketing or any instruction to use a medicine is subject to registration of such medicine in the National Drug Registry managed by the MoH. While the Pharmacists Ordinance uses different definitions to describe pharmaceutical products, it basically applies to any product designed for a medical purpose. Food products and medical equipment are governed by different regulations.

The Pharmacist Regulations (Preparations), 5746-1986 (the Preparations Regulations) provide the statutory framework and procedure for the registration and importation of medicines, as well as for the renewal and annulment of registration. The MoH is entrusted with conducting the registration process.

As part of the review process conducted by the MoH in the course of a registration process, the MoH will seek to verify, among other things, that the medicine is safe and effective, and that it was manufactured under proper manufacturing conditions (the manufacturing requirements are set out in the Pharmacist Regulations (proper manufacturing conditions), 5768-2008). The Preparations Regulations also stipulate the packaging and labelling standards of medicines, as well as advertising requirements. Advertising restrictions are also stipulated in legislation that deals with radio and television advertising rules, and specific procedures published by the MoH.

The Pharmacists Ordinance differentiates between the sale of prescription and non-prescription drugs. The MoH is authorised to determine that a certain medicine does not require prescription by a physician. Furthermore, the MoH is authorised to approve the sale of such medicines not in a pharmacy or by a pharmacist (over-the-counter (OTC) drugs). The sale of OTC drugs is regulated by the Pharmacist Regulations (the sale of non-prescription preparations not in a pharmacy or by a pharmacist), 5764-2004. These regulations refer, among other things, to the storage conditions, advertising, packaging and labelling of OTC drugs.

The prices of pharmaceutical products are subject, like any other product, to the Supervision of the Prices of Products and Services Act, 5756-1996 (the Price Supervision Act). The Price Supervision Act sets a procedure by which the government (in particular, the Supervisor of Prices at the MoH) may impose supervision on the price of a product. There are roughly three categories of pharmaceutical products that are subject to price supervision: prescription drugs are subject to the maximum price cap (Chapter E of the Price Supervision Act). Non-prescription drugs that are not sold over the counter must have any price increase approved (Chapter F of the Price Supervision Act). OTC drugs are not subject to any price cap, but it is necessary to provide the Supervisor of Prices with ongoing reports regarding their price, profitability, etc (Chapter G of the Price Supervision Act).

The National Health Insurance Law, 5754-1994 determines, among other things, the list of drugs that are included in the national health insurance (the health basket). The list of medicines that are included in the health basket is reviewed annually by a public committee (the health basket committee). The decision is based on a wide range of parameters, including medical, social and budget-related considerations. The Minister of Health is authorised, under certain conditions, to issue a decree for adding a certain drug to the health basket.

Another relevant piece of legislation is the Patents Law, 5727-1967 (the Patents Law), which regulates the licensing of patent rights. The Patent Law sets the conditions and procedure for the registration of patents, the scope of patent rights, and the commercialisation of patents. The Israel Patent Office is entrusted with enforcing the Patents Law.

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

The Pharmacists Ordinance and the Pharmacists Regulations mentioned above govern the sale of both prescription and non-prescription drugs, as well as the sale of OTC drugs. The Pharmacist Regulations (proper manufacturing conditions for pharmaceuticals), 5769-2008, among other things, sets terms for the distribution of pharmaceuticals. These regulations mandate adherence to the standards determined in European Commission Directive 2001/83/EC as dictated in the Good Distribution Practice guideline (GDP), Guideline on Good Distribution Practice of Medicinal Products for Human Use (2013/C68/01) (including any amendments thereto), in order to ensure that pharmaceutical products and raw materials used in the production of pharmaceuticals are distributed under proper conditions and in accordance with high standards of quality throughout the entire chain of distribution. These regulations further determine that one of the criteria for being granted approval by the MoH for the manufacture or distribution of pharmaceuticals is adherence to such GDP.

The sale, storage and distribution of pharmaceuticals by pharmacies is also regulated by other pieces of legislation such as the Pharmacist Regulations (issuance and transfer of dangerous drugs), 5743-1983 and Pharmacist Regulations (conditions for the opening and operation of pharmacies and medicine storage rooms), 5742-1982.

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

The legislation described above, inter alia, sets the conditions for operating in the relevant markets. Naturally, the need to obtain authorisation, in addition to the high standards that the legislation sets for such approval, may serve as a significant barrier for entry, resulting in a less competitive environment in many markets. In addition, the restrictions that the legislation imposes on the marketing of drugs, such as restrictions on advertising and the solicitation of medical staff, may also bear negatively on competition in the market. Patent law is also very influential in shaping the competitive environment in the sector, leading in many cases to high market concentration and limited price competition.

Competition legislation and regulation

4 Which legislation sets out competition law?

The Restrictive Trade Practices Act, 5748-1988 (the Antitrust Law) is the primary legislation that deals with competition. The Antitrust Law deals with four types of restraints on trade: restrictive arrangements, merger transactions, abuse of dominant position and concentration groups.

Chapter B of the Antitrust Law regulates restrictive arrangements (ie, arrangements that may adversely affect competition or that fall within one of the per se presumptions such as price fixing or market allocation). Restrictive arrangements must be approved in advance by the Antitrust Tribunal unless they fall within a statutory or block exemption, or receive a particular exemption from the Antitrust Commissioner (the Commissioner).

Chapter C regulates mergers and requires that the Commissioner be notified in advance of any transaction that falls under the definition of a 'merger', if it meets certain reporting thresholds. The Commissioner may block any notifiable merger that may significantly lessen competition in the relevant market.

Chapter D regulates unilateral actions by monopolies (firms possessing market share above 50 per cent), prohibiting abuse of a monopoly position (which includes predatory pricing, price discrimination, excessive pricing and tying).

Chapter D1 governs the regulation of 'concentration groups' – groups comprising of few competitors that dominate more than 50 per cent of a market that have been declared as such by the Commissioner (essentially, oligopolistic markets). Declaring a group of competitors as a concentration group enables the Commissioner to take certain measures and issue instructions to its members that are aimed at preventing harm to competition or promoting competition in the relevant market.

Following major social unrest relating to the cost of living in Israel, the Antitrust Law was significantly amended, granting the Commissioner new powers and narrowing the scope of antitrust immunity for certain sectors and arrangements. In particular, these amendments enable the Commissioner to conduct market surveys, regulate oligopolistic markets presenting a tendency towards price parallelism and initiate the imposition of structural remedies against monopolies (including divestment of key assets). During the last few years, the Israel Antitrust Authority's (the IAA) staff almost doubled in size, and the IAA's role as the key competition adviser to the government (including the MoH) was solidified and formalised by the Law for the Promotion of Competition and Reduction of Concentration Act, 5774-2013.

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

The government agency responsible for the implementation and enforcement of the Antitrust Law is the IAA.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

Violations of the Antitrust Law are a criminal offence and liability applies not only to corporations, but also to the individuals involved in the wrongdoing (including indirect criminal liability on senior officers). Criminal penalties include possible imprisonment of up to three years (five years in aggravating circumstances) and significant fines. Criminal enforcement is normally reserved for hard-core cartel offences, bid rigging and other gross violations of the Antitrust Law.

Apart from criminal enforcement, the IAA has a diverse set of administrative enforcement tools, including the following:

- A declaration of breach – this serves as prima facie evidence in any court proceeding, thereby facilitating private lawsuits against the parties to such agreements or practices. The declaration may also serve subsequent criminal or civil proceedings initiated by the IAA.
- A consent decree – this is entered into between the IAA and an alleged antitrust offender. Such decree is an alternative for a criminal or administrative action and it may include fines and undertakings by the alleged offender. The decree is subject to approval by the Antitrust Tribunal.
- Injunctive relief – the IAA may apply to the Antitrust Tribunal seeking a restraining order aimed at preventing or terminating violations of the Antitrust Law.
- Monopoly instructions – when a monopoly is involved, the Commissioner may issue instructions regarding actions necessary to prevent harm to competition or to the public. Under the 2011 amendment to the Antitrust Law, in certain oligopoly markets, the Commissioner may declare the oligopoly members a 'concentration group' (a small group of competitors dominating more than 50 per cent of a market that have been declared as such by the Commissioner under Chapter D1 of the Antitrust Law) and issue directives aimed at preventing harm to competition or increasing competition.
- Structural remedies – the Antitrust Tribunal, on the request of the Commissioner, is authorised to instruct a monopoly or a member of a concentration group to sell an asset (including IP rights), generally, in order to prevent harm or a possibility of significant harm to competition or the public.
- Monetary payments – the Commissioner may unilaterally impose significant monetary payments on companies and individuals for a wide range of antitrust offences, such as illegal restrictive arrangements and abuse of dominant position. The payment can reach up to 1.02 million shekels for individuals and up to 24.5 million shekels for corporations.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Section 50(a) of the Antitrust Law states that an act or omission contrary to the provisions of the Antitrust Law shall constitute a tort in accordance with the Tort Ordinance (New Version) (the Tort Ordinance). The same applies to any breach of conditions or directives issued by the Commissioner or by the Antitrust Tribunal, and any violation of consent decrees entered into with the Commissioner. Such violations are the basis for claims for damages or other injunctive relief.

Accordingly, private parties may file a lawsuit against antitrust offenders seeking compensation for damages incurred as a result of an antitrust violation or apply for an injunction order to prevent such damages. The Class Actions Law, 5766-2006 provides that a person or consumer organisations may, under certain conditions, file a class action on behalf of a class of plaintiffs and seek damages for breach of the Antitrust Law.

In addition to establishing a breach of the Antitrust Law, civil liability requires proof of harm and of causal link between such harm and the anticompetitive behaviour. The Tort Ordinance grants damages according to the harm actually incurred, and generally does not grant exemplary or punitive damages. Damages will, however, normally include interest and will be consumer-price index-linked according to the Interest and Linkage Adjudication Law, 5721-1961.

As mentioned above, the IAA can issue a declaration of breach under the Antitrust Law, which serves as prima facie evidence in any court proceeding, thereby facilitating private lawsuits against the parties to such agreements or practices.

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

In 2011, Israel witnessed a wave of social unrest, which resulted in the formation of three public committees, particularly in the area of competition, including the Trajtenberg Committee for Socioeconomic Change. As a result of the recommendations made by the Trajtenberg Committee, a new division at the IAA was formed – the Competition Division, which is responsible for conducting sector-wide inquiries. Although such inquiries are still in their infancy, the IAA has indicated in the past that it may pursue a sector-wide inquiry into the health sector.

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

It is very common for the IAA to consult customers and to take into account their position in the course of merger investigations, as well as in the context of other enforcement actions. IAA economists will often enquire of customers over the phone as to their views on a matter and issue customers supplementary data requests.

Any customer may also provide the IAA information voluntarily. The IAA is mostly interested in factual information rather than opinions

on the competitive implications of a proposed transaction. In addition, various social organisations (such as consumer organisations) were granted a formal standing under the Antitrust Law to contest approvals of transactions by the Commissioner.

Consumer organisations are also allowed to file antitrust-based class actions, although these organisations have not been very active in antitrust litigation to date.

Review of mergers

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

The Commissioner uses the same methodology in reviewing mergers in the pharmaceutical industry as it does in other industries. However, sector-specific characteristics will be taken into consideration by the Commissioner when implementing this methodology. Among other things, the Commissioner will take into account the potential barriers to entry (which may be more substantial in the sector due to the strict authorisation requirements, the vast investments needed to develop medicines and the difficulties facing potential entrants, as a consequence of intellectual property rights of incumbent firms).

Since most merger transactions in the sector are foreign-to-foreign transactions, the IAA is often in an inferior position to gather and assess information relating to the transaction. This is especially true in cases that involve two firms that are still in the R&D stage. In such cases the IAA may prefer to await a decision by the US or EU authorities before rendering its decision.

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

Generally speaking, the Commissioner applies the same market definition methodology in all sectors, including the pharmaceutical sector. Market definition is based on cross-elasticity of demand between pharmaceutical products. The relevant market includes the narrowest group of products, in which a hypothetical monopolist would be able to profitably raise prices (small but significant non-transitory increase of price test). As a practical indication, the IAA will use an increase of between 5 and 10 per cent for a period of one year. In September 2016 the IAA published for public comment a draft study on the methodology for defining markets utilising econometric models of demand. The draft study demonstrates the use of an econometric model for the evaluation of demand elasticity on the basis of consumer behaviour in order to define markets. The IAA notes, however, that the form of analysis demonstrated in the draft study is remarkable in its complexity and breadth and falls outside the scope of the IAA's resources in its day-to-day operations. Since in many cases cross-elasticity of demand cannot be measured accurately, the Commissioner will normally rely on qualitative 'practical indicators'. These include the purpose and use (functionality) of the products or services in question, the objective physical properties of the products or services, their price, the structure of supply and demand in the market, and other characteristics of the product that may indicate the extent of substitutability between them. These practical indicators are supplemented in complex cases by econometric analysis (price comparisons, critical loss analysis, etc).

In the specific context of the pharmaceutical industry, the Commissioner also relies as a starting point on standard classifications such as the anatomical therapeutic chemical (ATC) classification system. However, in relation to some types of pharmaceuticals such as targeted therapies used in the oncology sector, the ATC classification system serves as a highly imperfect proxy for substitutability. In such cases, the Commissioner is likely to examine a drug's mechanism of action, line of treatment indication and other factors in order to formulate a conclusion regarding substitutability. The Commissioner also differentiates between OTC and prescription drugs, which will generally be part of separate product markets (see exemption of a restrictive arrangement between Kupat Holim Klalit, Vitamed Pharmaceutical Industries Ltd and others, 2002).

The relevant geographic market is in most cases global, but the IAA will inquire as to which pharmaceutical products are actually registered and authorised by the MoH for sale in Israel. In *Teva Pharmaceuticals/ Honeywell*, the IAA ignored global overlap, because the acquired firm's medicine was not authorised for sale in Israel. If the scope of actual competition in Israel is limited, the IAA will seek to verify that global competitors are likely to register in Israel if a price increase occurs.

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

Considering efficiency-based arguments is not required in order to approve a proposed merger that does not pose a threat of harming competition. Efficiency-based arguments may be taken into account if the merger is likely to harm competition. In such case, these arguments may serve as defence. Thus, if the IAA is convinced that the efficiencies directly deriving from the merger outweigh the potential harm to competition, the merger may be approved. In order to enjoy the efficiency defence, one must meet certain cumulative conditions: (a) the efficiency must be merger-specific, in the sense that the parties cannot obtain similar efficiencies in any other way; and (b) the efficiency must be significant, timely and such that the benefits will mostly be passed on to the consumers and outweigh the harm inflicted on them by the loss of competition. We assume that efficiency-based arguments regarding research and development may, in theory, fall under the efficiency defence, provided these conditions are met. However, thus far the efficiency defence has not been accepted by the IAA with respect to a merger that was likely to significantly decrease competition.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

In 2011, the IAA published the Horizontal Mergers Guidelines, which describe the theoretical economic and legal foundations upon which the IAA's merger review is based.

According to the Horizontal Mergers Guidelines, the core purpose of merger review is to prevent the creation or enhancement of market power. The guidelines further explain that such market power can be exercised either unilaterally (ie, 'unilateral effect', which is the ability of a merged firm to profitably and unilaterally raise its prices) or collectively (ie, 'coordinated effect', which is the formation, preservation, or reinforcement of an oligopolistic equilibrium).

Generally speaking, a horizontal overlap in a market in which only few competitors operate, and to which there are significant barriers to entry or expansion, is treated suspiciously. However, the guidelines stress that the merger investigation does not rest solely on static analysis. Therefore, when the initial assessment yields that the merger raises significant concerns, the IAA will enter a more detailed analysis of the 'dynamic aspects' (ie, the possibility that the entry or expansion of existing players in the market will mitigate the immediate and potentially harmful effects of the merger).

The analysis of entry and expansion will focus on a variety of entry and switching barriers, including regulatory barriers, scale economics, network effects, strategic behaviour by incumbent firms, branding, access to essential inputs, and much more.

The Horizontal Mergers Guidelines also acknowledge potential competition concerns. Such concerns may arise when the merger eliminates potential entry that was imminent (actual potential competition) or when it eliminates the competitive threat embedded in such an entry (perceived potential competition).

While the IAA has increased the use of econometric analysis in recent years, it still relies significantly on direct evidence such as internal documents and market surveys.

Since most mergers in the pharmaceutical sector were made between international pharmaceutical companies, competitive problems (if there were any) were usually dealt with by other competition authorities. Therefore, there are no available examples of mergers between pharmaceutical companies that the IAA blocked.

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

There are no clear rules or precedents relating to mergers between firms at the R&D stage. However, such mergers are likely to raise potential competition issues. Among other things, the IAA will likely seek to understand how advanced the parties are in the R&D of the relevant product (the more advanced the parties are the more likely it is that the parties will be deemed competitors – see exemption of a restrictive

arrangement between Andromeda Biotec Ltd and Teva Pharmaceutical Industries Ltd, 2009). The IAA will also seek to establish how many other firms are investing R&D resources on substitutable products and the size of the potential market for the developed product.

According to the Horizontal Mergers Guidelines, the IAA considers companies who are expected to enter the market within 12 to 18 months after the merger as potential competitors for the merging companies. However, the IAA may take into account shorter or longer periods of time, depending on the specific characteristics of the case and industry. In the context of a merger between two firms, the IAA will usually view them as potential competitors even if competition between them is expected to occur within a longer period of time.

In the pharmaceutical sector, a key factor in assessing potential competition is the phase of clinical research. Roughly speaking, if the merging firms are on phase II clinical trials or at a more advanced phase, the IAA is more likely to investigate potential competition between them.

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

The Antitrust Law requires the Commissioner to approve a potentially harmful merger, if such potential harm can be avoided by proposed conditions.

In 2011, the IAA published the Guidelines on Remedies for Mergers that Raise a Reasonable Concern for Significant Harm to Competition.

The document outlines the governing legal principles in the area of merger remedies, from which two stand out:

- the IAA is authorised to request remedies only if the merger, as it was originally proposed, raises a real danger that competition will be significantly harmed. In other words, the IAA may impose conditions only for mergers that it can otherwise block; and
- remedies are preferable whenever they are capable of mitigating the harm to competition.

The guidelines explain that the decision of whether to impose remedies and what sort of remedies are suitable in a particular case is based on the specific circumstances of the case at hand. However, the guidelines state the general preference for structural remedies (such as the divestment of overlapping business) over behavioural remedies. The IAA alleges that structural remedies are normally more effective as they deal with the 'disease' and not merely the symptoms, do not require complex and ongoing monitoring, require fewer public resources, and are executed within a defined and normally short period. However, the IAA acknowledges the fact that in certain instances, behavioural remedies or a combination of behavioural and structural remedies would be more appropriate.

As explained, there is very limited case law involving harmful mergers in the pharmaceutical industry. However, licensing agreements were used in certain cases as a remedy in international transactions in other sectors. For instance, in 2009, the Commissioner approved a merger between Osem Investments Ltd (a public company controlled by Société Des Produits Nestlé SA) and Materna Laboratories Ltd (a leading local manufacturer, active in the production and marketing of baby food), inter alia, under the condition that Nestlé enter into a licensing agreement with an independent third party for the dstribution of its Gerber products in Israel. The purpose of the licensing condition was to mitigate the loss of potential competition between Nestlé and Materna as a result of the merger.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

Merger reporting requirements may arise with respect to 'merger transactions' that meet certain filing thresholds. A merger transaction is defined in the Antitrust Law, inter alia, as 'acquisition of the principal assets of a company by another company'.

According to the Commissioner Guidelines for Reporting and Evaluating Mergers 2007, the phrase 'principal assets of a company' refers to the substantive economic aspect (ie, whether the transaction effectively transfers a line of business or assets that are crucial for the acquired business to compete in such line of business). Therefore, the acquisition of patents may constitute a merger transaction in certain circumstances.

Anticompetitive agreements

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

Agreements that do not fall under the definition of merger transaction are governed by the restrictive practices chapter. Section 2(a) of the Antitrust Law defines any arrangement that may decrease competition as a restrictive arrangement, subject to certain conditions. In addition, section 2(b) of the Antitrust Law sets irrefutable presumptions of harm to competition, when the restriction in the agreement relates to prices, profits, market allocation, quotas and other cartel restrictions. In accordance with the Supreme Court ruling in *Shufersal*, section 2(b) of the Antirust Law applies only to horizontal arrangements. Vertical arrangements, as well as horizontal arrangements that falls outside of the irrefutable presumptions set under section 2(b), are reviewed based on their probable effects on competition in accordance with section 2(a) (the court, however, left open the possibility that section 2(b) could apply to vertical arrangements in 'rare circumstances'). The definition of restrictive arrangement was given a broad meaning, so that almost any form of collaboration between competitors, as well as many vertical arrangements, would be deemed a restrictive arrangement.

Section 3 of the Antitrust Law details several categories of arrangements that would not be deemed restrictive arrangements (often referred to as 'statutory exemptions'). Among the exempted categories are restrictions relating to the licensing of intellectual property, intragroup agreements and more.

Additionally, the Commissioner enacted several block exemptions, which exempt certain kinds of restrictive arrangements that meet certain conditions, including market share thresholds. Notable block exemptions that may be more relevant to the pharmaceutical industry are the JV block exemption and the R&D block exemption.

A restrictive arrangement, which does not fall under a statutory or block exemption, must be approved in advance by the Antitrust Tribunal or receive a particular exemption from the Commissioner. In assessing the possible competitive outcome of an agreement the Commissioner will seek to verify that the arrangement has legitimate business justification (ie, it is not a 'naked restraint') and that it does not raise significant anticompetitive concerns. The competitive assessment will generally be similar to the assessment made in merger investigations, although the legal standard to block an arrangement is lower.

18 To what extent are technology licensing agreements considered anticompetitive?

There are no particular guidelines regarding technology licensing agreements. The statutory exemption set in section 3(2) of the Antitrust Law exempts restrictions relating to the licensing of certain IP rights (eg, patents, trademarks, copyrights), subject to certain conditions. In addition, certain block exemptions (in particular, the R&D block exemption and franchise block exemption) may also apply to certain kinds of technology licensing agreements.

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

Co-promotion and co-marketing by competitors may raise competitive and legal considerations under the restrictive arrangement chapter. Certain block exemptions, such as the JV block exemption, may apply to these practices, subject to certain conditions (in particular, market share thresholds). Co-marketing arrangements are treated more harshly under this block exemption, which applies to such arrangements only when the joint marketing is part of a more comprehensive integration. This requirement stems from a general perception of joint marketing agreements as a cartel-like mechanism to achieve price uniformity.

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

The Israeli antitrust laws apply to any form of collaboration among competitors, including R&D, joint manufacturing or purchasing, and the exchange of information between competitors. As a rule of thumb, the larger the combined market share of the parties to the arrangement and the more concentrated the relevant market, the greater the likelihood that the arrangement will not enjoy a block exemption and will come under detailed scrutiny by the IAA.

In 2012, the Antitrust Commissioner opposed a market data sharing scheme reached between pharmaceutical manufacturers and importers and MarketWatch, a company that provides business analysis and market surveys. The initiative involved a very detailed information exchange that the Commissioner argued was likely to reduce competition in what he described as very concentrated markets.

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

Typically, vertical price restrictions (especially minimum or fixed retail price maintenance) and exclusivity agreements are at the centre of attention. Parameters that are relevant to the assessment of such agreements include the market shares of the relevant parties, the degree of concentration in the markets, the entry and expansion barriers, purpose of such restrictions, and the degree of price uniformity in the market.

Since the Supreme Court ruling in *Shufesral*, which generally removed the applicability of the irrefutable presumptions of harm to competition (section 2(b) of the Antitrust Law) from vertical arrangements, thus making resale price maintenance more readily accessible to parties, the IAA has acknowledged the need for clearer guidance on vertical arrangements. Accordingly, in January 2017, the IAA published draft guidelines on resale price maintenance, focusing on the manner in which minimum and fixed resale price maintenance should be analysed and the circumstances in which it will tend to view such arrangements as not causing harm to competition.

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

Israeli law does not set any particular rules on this matter. However, the wording of the law, as well as the governing principles by which it is interpreted by the courts, suggest that a 'reverse payment' settlement between competitors may constitute a restrictive arrangement.

In 2005, the Antitrust Tribunal struck down an application relating to a settlement of IP litigation between the two leading companies in the water counters market – Arad Ltd and Madei Vered. As part of the settlement, Madei Vered (the defendant) was supposed to cease its activity in the water counters field, including its activity in relevant markets that were not the subject of the IP litigation, in return for a substantial sum of money.

The Antitrust Tribunal determined that this settlement, which implements a 'reverse payment' mechanism, lacked any legitimate commercial justification, and that the sole motive for the arrangement was the elimination of the existing competition in the market.

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

Anticompetitive exchanges of information are not necessarily more likely to occur in the pharmaceutical sector in Israel. There is a relatively large degree of market transparency in this sector, as some players are public and others are state funded or controlled. The market regulator also plays an important role in increasing transparency. As a result of the sector being highly regulated, key competitive factors become public (eg, drug maximum prices, which are regulated). However, this type of market transparency does not necessarily harm competition, and in any event, does not breach the Antitrust Law, given that the exchange is not made by way of an arrangement between competitors, but by the regulator disseminating the information among competitors.

Anticompetitive unilateral conduct

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

Generally speaking, unilateral conduct may only be illegal if it is carried out by a monopoly. Thus, a firm with considerable market power is often free to engage in exclusionary or exploitative practices, as long as its market share does not exceed the 50 per cent threshold (see question 25, and subject also to the restrictive arrangements chapter).

Unilateral conduct is governed by Chapter D of the Antitrust Law, which deals with monopolies. Monopolies are not illegal under the Antitrust Law. However, unilateral conduct by a monopoly is illegal if it falls under one of the following categories:

- refusal to deal: section 29 of the Antitrust Law prohibits 'unreasonable refusal to supply or purchase' a product in which a monopoly exists. A reasonable refusal to deal was described in the case law as one 'that is compatible with the principles of the antitrust laws and free competition'. If refusal to deal has anticompetitive objectives or outcomes, it usually will not be considered reasonable. A refusal to deal with rivals is not necessarily 'unreasonable'. Usually, the duty to deal with rivals is examined under the essential facilities doctrine; and
- abuse of a monopoly position (section 29A of the Antitrust Law), which is subdivided into two categories:
  - a substantive effects-based test, according to which any practice employed by a monopoly that may injure competition or the public constitutes an illegal abuse of monopoly power (section 29A(a) of the Antitrust Law); and
  - section 29A(b) of the Antitrust Law stipulates specific practices that are deemed abusive when engaged by a monopoly (eg, tying, predatory pricing, price discrimination). While according to the case law there is an irrefutable presumption of injury to competition with respect to these practices, they are defined very vaguely, in a way that leaves room for economic analysis in their context too.

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

The Antitrust Law states that a firm is deemed a 'monopoly' if it possesses a market share exceeding 50 per cent in a relevant market, regardless of whether such firm has monopoly power. The Commissioner may proclaim a certain firm a monopoly, but such proclamation is only declaratory. The proclamation serves as prima facie evidence that the firm in question is indeed a monopoly, in any legal proceeding.

On the other hand, a firm that does not have a market share above the statutory threshold is not considered a monopoly, even if it possesses significant market power. The Minister of Industry, Trade and Labour may set a lower market share threshold for certain goods or services. This power, however, has not yet been executed.

As mentioned, the Commissioner may regulate oligopolistic markets by declaring that a small group of competitors dominating more than 50 per cent of a market are a 'concentrated group'. Such declaration requires demonstrating that 'conditions supportive of limited competition' exist, and that there are remedies that can enhance competition or prevent further injury to competition. According to the Antitrust Law, 'conditions supportive of limited competition' would

Update and trends

In recent years, private parties have begun to take a more prominent role in the antitrust landscape. In April 2014, the IAA published guidelines on the IAA's enforcement policy regarding excessive pricing. The guidelines established that the IAA views the charging of excessive prices by monopolies, under certain conditions, as illegal unfair pricing. Soon thereafter, dozens of class actions on the grounds of excessive pricing were launched. The Central District Court recently certified a class action against Tnuva, Israel's largest dairy producer and a proclaimed monopoly in the dairy sector, relying in part on the guidelines.

Following changes in the IAA's leadership, the IAA's policy towards excessive pricing changed and the IAA is less inclined to enforce the prohibition. However, due in large part to courts' receptiveness to excessive pricing claims, it seems that the increase in class actions brought against dominant firms on the grounds of excessive pricing is likely to continue. This trend has yet to reach the pharmaceutical sector, for now being concentrated mainly on the food and consumer good sectors. Yet if excessive pricing claims continue to gain traction and fall upon welcoming ears, it is possible that pharmaceutical companies may come under the radar of class action plaintiffs. The lack of such claims against pharmaceutical firms can be explained by the fact that drug prices are regulated, with a cap set by the government. Additionally, the development of pharmaceutical products requires significant R&D expenses and carry significant risks, which provide a legitimate explanation for the 'high' prices charged.

exist, among other things, where there is an entry barrier to the market with two additional components, such as switching costs, cross-holdings between competitors, market share symmetry, homogenous products, or the transparency of terms and conditions in the market.

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

No. As explained in the previous answer, a firm is deemed a 'monopoly' if its market share exceeds 50 per cent of the relevant market. Thus, a decision on whether a patent holder is a monopoly will be made in accordance with its position in the market, and will not be affected by the mere holding of a patent.

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

The exercise of a patent right within the grant of a patent or the attempt to register a patent unto themselves, will normally not be deemed an abuse of a dominant position. Nonetheless, a fraudulent application or an abuse of the patent beyond its statutory scope may be considered an abuse of a dominant position.

In a recent case, *Unipharm v Sanofi* (CC (Central) 33666-07-11), the Central District Court left open the question of whether an innovator drug company that files a 'weak' patent application in order to delay the entry of competing generic companies into the market could be held liable for abuse of dominant position.

As long as the enforcement of the patents is done within the grant of the patent, it is generally not considered an antitrust violation.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

The general rule is that an authentic registration of a patent, as well as the enforcement of a legal and valid patent, is not deemed an abuse of a dominant position. The basic premise is that if the patent owner only introduces an artificial change of the patented product to block competition, such practice would be handled by the provisions of the patent law, and not through the overriding application of the Antitrust Law.

However, in the recent case of *Unipharm v Sanofi*, the Central District Court, in a precedential decision, imposed antitrust liability on a patent holder. It involved a claim brought by Unipharm, a generic pharmaceutical company, against the innovator pharmaceutical company, Sanofi, in which Unipharm argued, among other things, that Sanofi's patent application regarding the blockbuster drug, Plavix, was, in essence, a false attempt to prolong the term of protection of Plavix's original patent. The decision deals with the legal duties and restrictions imposed upon an innovator pharmaceutical company in its attempt to utilise intellectual property law in order to prevent or delay the entrance of competing generic drugs into the market.

The court decided that Sanofi misled the Patent Office by knowingly submitting incorrect information and did not disclose required information regarding the circumstances of the discovery that led to the patent application in question. In doing so, Sanofi artificially increased the chances that its patent application would be accepted, burdened the process of opposing the patent and delayed the entrance of generic companies (including Unipharm) into the market, thereby de facto extending its monopoly status. Such actions, the court decided, constitute an abuse of dominant position under the Antitrust Law and grant Unipharm a legal claim to Sanofi's illegally obtained profits in the framework of unjust enrichment law. Sanofi appealed the court's decision and the case is currently pending before the Supreme Court.

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

In principle, a patent owner is not restricted by the Antitrust Law in marketing a generic drug in addition to the patented drug. However, the Commissioner is authorised to instruct a patent owner who is also a monopoly not to issue a generic drug if such action on the part of the monopoly is likely to substantially injure competition.

A patent owner may also appoint a third party to market its generic drug, but this appointment will be reviewed by the IAA, among others, under the restrictive arrangements chapter. The focus of such review would be to ascertain whether the appointment diminishes potential competition between the patent owner and the appointee.

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

Objective justification is an essential part of the analysis of vertical restraints under the Antitrust Law. The efficacy and safety of drugs may often justify vertical restrictions in a pharmaceuticals distributor agreement. Additionally, certain advertising restrictions, which are normally not authorised in a vertical setting, may be deemed necessary in the context of the pharmaceutical sector.

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

Not applicable.

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The regulatory framework governing the manufacturing and marketing of pharmaceutical products in Italy is set out by Legislative Decree No. 219/2006 (the Code of Pharmaceuticals), which implemented Directive 2001/83/EC.

The Code of Pharmaceuticals governs, inter alia, the national, decentralised and mutual recognition procedures for the issuance of marketing authorisation (while the centralised procedure is directly governed by Regulation (EC) No. 726/2004); the procedure and conditions for the issuance of manufacturing authorisation; and the conditions for advertising of pharmaceuticals, pharmacovigilance requirements, etc.

Matters on pricing and reimbursement of pharmaceuticals fall entirely under the competence of member states, which set out their own rules autonomously from EU institutions or bodies.

In Italy, once a drug is authorised for marketing, it must be classified by the Italian Medicines Agency (AIFA), which is the national regulatory authority, under a specific category for purposes of reimbursement by the National Health Service (NHS): drugs in Classes A and H are reimbursed by the NHS; whilst Class C drugs are not. Further, for a drug to be reimbursed by the NHS, its price will have to be set through mandatory negotiations between the marketing authorisation's holder (MAH) and AIFA, as provided for by Law No. 326/2003 and according to the economic criteria set out in CIPE's Resolution of 1 February 2001 (CIPE Resolution). It is AIFA's exclusive responsibility whether to include a drug under a refundable class and, in that case, what its price should be. For generic pharmaceuticals to be classified under the same class of their corresponding originators, their price must be set at least 20 per cent lower than the originators' price. Notably, MAHs of drugs reimbursed by the NHS may have to 'pay-back' significant amounts to the NHS if certain budget thresholds both public and related to each MAH – established yearly – are exceeded.

If a drug is not reimbursable by the NHS (ie, it is Class C), the MAH is free to set the price at its own discretion (though certain statutory limitations on price increases still apply).

More recently, Law Decree No. 158/2012 has introduced a new class named Class C-not negotiated (C- nn), where new drugs are automatically included as soon as they are authorised. In this way, they can be placed on the market as non-reimbursed drugs pending the AIFA's decision on reimbursement and prices. A fast-track procedure is available for certain innovative and orphan drugs. Pursuant to Law No. 648/1996, a drug that is not authorised in Italy may, nonetheless, be provided to patients, and be fully reimbursed by the NHS, if:

- there is no valid, authorised therapeutic alternative; or
- (if a valid, authorised therapeutic alternative does exist) the drug is intended to be used 'off-label' (ie, for a therapeutic indication other than that it was authorised for), on the condition that the off-label therapeutic indication is known and consistent with national and international medical research, and that the off-label marketing of the drug is 'appropriate' and economically viable.

The AIFA assesses whether such conditions are satisfied and, if its opinion is favourable, the drug is included in a specific list and can thereafter be supplied to patients.

It is AIFA's responsibility to enforce the rules described above. This includes, inter alia: granting authorisations to manufacture and trade pharmaceuticals and to conduct clinical trials; monitoring pharmacovigilance activities; supervising the advertising of pharmaceuticals; and ensuring compliance with the restrictions applicable to the public expenditure for pharmaceuticals, etc. AIFA's decisions can be challenged, in the first instance, before the Regional Administrative Court of Lazio and, on appeal, before the Council of State.

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

Yes – the distribution chain of pharmaceuticals sold to patients in Italy includes wholesalers, depositaries and pharmacies. Wholesalers and depositaries must be authorised by the competent Italian regional government pursuant to, respectively, articles 100 and 108 of the Code of Pharmaceuticals.

The main difference between wholesalers and depositaries is that the former directly purchase drugs from MAHs with the purpose of selling them to pharmacies, while the latter merely store and keep drugs in custody, pursuant to deposit agreements with the MAH. Consequently, only wholesalers are responsible for complying with the public service obligation provided for by article 105 of the Code of Pharmaceuticals, pursuant to which wholesalers have a duty to ensure availability of a wide range of pharmaceuticals (namely, 90 per cent of the authorised drugs that are reimbursed by the NHS) so as to ensure prompt supply (within 12 hours of the request) to pharmacies located in a given area. Brokers cannot be characterised as either wholesalers or depositories, since they do not materially possess the pharmaceuticals. In fact, they do not need authorisation.

In Italy, the opening of a pharmacy (ie, a store for the sale of all categories of pharmaceuticals) is subject to authorisation from the local health authority on condition that a number of requirements – set out by Law No. 362/1991 and implementing regulations – are fulfilled, in particular:

- the number of pharmacies cannot exceed a ratio of one to every 3,300 citizens in each given area;
- a pharmacy can only be owned by either pharmacists or natural entities, partnerships or limited liability cooperatives made by pharmacists; and
- no person or entity can manage more than four pharmacies within the province where it has its registered office.

Other requirements pertain to the organisation, the internal architectural structure and the availability of certain appliances or technologies within the store.

In Italy, 'para-pharmacies' (ie, stores that are not authorised as pharmacies) are only allowed to sell non-prescription drugs (Law Decree No. 223/2006). They are also subject to the fulfilment of the structural, organisational and technological requirements provided for by a Ministerial Decree of 8 March 2012.

Wholesalers and pharmacies are entitled to a mark-up on drugs reimbursed by the NHS. The amount is set out by law as a percentage of the final price to consumers. They are also subject to payback

obligations if the public expenditure for the purchase of pharmaceuticals exceeds certain regional and national thresholds. A review of the remuneration system for wholesalers and pharmacists is expected by 1 January 2018.

Hospitals and other healthcare organisations purchase pharmaceuticals through the public tender procedures, according to the Public Procurement Code (Legislative Decree No. 50/2016).

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

Please see the following list:

- the rules concerning the off-label use of pharmaceuticals (see question 1), which state that AIFA can create a list of drugs whose off-label or unlicensed use is, nonetheless, reimbursable by the Italian NHS under certain circumstances (Law No. 648/1996 as amended by Law Decree No. 36/2014, issued following the *Avastin/Lucentis* case. See question 20);
- the rules concerning the marketing of generic drugs, under two perspectives:
  - data exclusivity and market exclusivity: pursuant to article 10 of the Code of Pharmaceuticals, whoever wants to get the authorisation to market a generic drug:
    - cannot refer to the results of the preclinical and clinical trials already filed by the corresponding originator (and instead simply file the bio-equivalence study) unless eight years have elapsed from the date the originator was authorised; and
    - cannot, in any case, put the generic on the market until 10 years (or 11 under certain conditions) from the same date;
  - patent protection: pursuant to Italian patent law, the holder of an originator's patent can prevent the marketing of the correspondent generic drugs for a period of maximum 20 years from the deposit of the patent; plus an additional period of a maximum of five years if a complementary protection certificate (CPC) is granted;
- the rules governing the matters of pricing and reimbursement of pharmaceuticals, which involve mandatory negotiations with AIFA (see questions 1 and 28); and
- the rules disciplining the opening and operations of pharmacies and para-pharmacies (see question 2), which have been subject to continuous debate in Italy as to their indispensability and proportionality.

Competition legislation and regulation

4 Which legislation sets out competition law?

Competition law in Italy is set forth in Law No. 287 of 10 October 1990 (Law 287/90), which provides for the Italian equivalent of articles 101 and 102 TFEU as well as national merger control rules.

Law 287/90 applies horizontally to all business sectors: there are no specific competition rules or exceptions applicable to the pharmaceutical sector. However, as mentioned above, sector regulation may affect or influence the interpretation and application of certain competition rules with respect to the pharmaceutical industry.

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

The Italian Competition Authority (ICA) is responsible for investigating and monitoring compliance with general competition law across all sectors (including pharmaceutical). Anticompetitive agreements, abuse of dominance and domestic merger control fall under the ICA's jurisdiction. Neither AIFA nor other sector authorities have any overlapping competences in that regard.

Further, since 2012, the ICA has been assigned new advocacy powers, which, ultimately, entitle it to directly challenge before administrative courts public regulatory measures that may restrict competition and free circulation of services disproportionately, or in a way that is contrary to competition law and principles (article 21-bis of Law 287/90). In case AS1257 the ICA challenged certain of AIFA's regulatory measures concerning reimbursement of certain drugs for hepatitis C and, as a result, AIFA amended and substituted the previous resolution contested by the ICA.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

After a thorough investigation into whether certain conducts or agreements infringe competition law, the ICA can order that the anticompetitive conduct or agreements cease, as well as impose fines of up to 10 per cent of the company's turnover (article 15 of Law 287/90).

Failure to comply with the cease-and-desist order referred to above would trigger fines of at least twice the original amount (though the fines would be capped at 10 per cent of the company's turnover) and, ultimately, lead to the compulsory suspension of the company's activities for a maximum of 30 days.

The ICA may also impose urgent interim measures if certain conduct, which at first glance is likely to constitute an infringement of competition law, is also likely to cause serious and irreparable harm to competition (article 14-bis of Law 287/90).

For example, at the outset of an investigation against an anticompetitive scheme between drug's distributors (case I678 of 20 September 2007, Distribution of non-prescription drugs to para-pharmacies), the ICA ordered the distributors to provisionally stop rejecting requests to supply non-prescription drugs to para-pharmacies, pending the investigation. Also, in a proceeding for abuse of dominance (case A364 of 21 March 2007, *Merck-Active ingredients*) the ICA provisionally required Merck to license certain active ingredients to a competitor for a certain use (though the investigation ended with a commitment decision).

Within three months of opening an investigation, the investigated parties may propose commitments to remove the concerns for competition raised by the ICA. If accepted by the ICA, the commitments will be made binding by a decision that will neither impose a fine nor ascertain any infringement. However, if the ICA were to characterise the alleged infringement as serious, it would be precluded by law from accepting any commitments and would have to proceed with imposing a fine (article 14-ter of Law 287/90).

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Private parties harmed by anticompetitive conducts may take two routes:

- they may file a complaint with the ICA substantiating the alleged infringement and requesting the ICA to initiate a public investigation to bring the infringement to an end, possibly by means of urgent interim measures (article 12.1 of Law 287/90); or
- they may claim restoration of the harm suffered because of the infringement before national courts. To this end, damages claimants can now take advantage of the new prerogatives and facilitations set out in Legislative Decree No. 3/2017, which implements the Antitrust Damages Directive (2014/104/EU) in Italy.

The ICA's proceedings mentioned above (see question 6) were prompted by private complainants and associations of affected traders and consumers. Also, recently the implementation of the Antitrust Damages Directive has prompted private damages actions by the NHS against competition law infringers to receive compensation for the excessive charges paid by taxpayers.

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

Yes – the ICA has the power to conduct industry-wide inquiries in every sector (including pharmaceutical) to identify possible competition concerns.

The first ICA's industry-wide inquiry into the pharmaceutical sector was in November 1997 (IC14 – *Pharmaceutical Sector*). It focused on certain regulatory and legislative restrictions that were deemed disproportionate or inadequate to attain the underlying public goals and instead stifled competition along the supply chain.

The second ICA's inquiry into the pharmaceutical sector was closed in May 2016 (IC50 – *Market for Human Vaccines*). It was launched to

assess whether the market for human vaccines, particularly those mandatory or highly recommended pursuant to public policies, required antitrust intervention.

The outcome of the latter inquiry was that the market for the manufacture of said vaccines is oligopolistic: the four largest players are private multinationals that hold 80 per cent of the overall relevant market. Further, the ICA identified several information asymmetries between manufacturers and buyers (either the NHS or private buyers) with respect to the cost structure of the vaccines, their substitutability (ie, depending on the specific type of pathology addressed thereby), the prices negotiated with each buying entity and, more generally, the data required to assess the viability and necessity of vaccines. The ICA found that such information asymmetries incentivise certain manufacturers' patent management and product-offering strategies that maximise inefficient product differentiation and price discrimination (or tiered pricing). These features, coupled with a lack of adequate regulation on issues such as the classification of vaccines, the entry of generics and the mandatory negotiation of prices with the AIFA, reduce competition and increase prices in the Italian pharmaceutical market.

To address such concerns, the ICA suggested, among other things, a regulatory intervention at either national or supranational (EU) level aimed at filling the information asymmetries and so reducing the vaccine manufacturers' exploitation of their market power. In particular, the ICA recommends the introduction of mandatory negotiation of prices with AIFA for essential human vaccines (which are not subject to such a procedure at present) and to increase transparency in the technical assessment of the vaccines' necessity and on the entry of generics.

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

NGOs, as well as trade associations or consumer groups, play an important role as they are entitled to file complaints with the ICA to signal possible competition law infringements. They can also request to intervene in ongoing proceedings, if they prove to have a qualified interest. Further, all such groups or associations may go to national courts to claim damages; request that anticompetitive agreements be declared null and void; and request urgent interim measures. To this end, consumer groups may also bring class actions to courts.

Review of mergers

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

There are no sector-specific merger control rules applicable to mergers between pharmaceutical companies.

Nonetheless, the ICA duly takes into account specific features of the pharmaceutical industry when assessing concentrations between undertakings in that sector. In particular, sector regulation on the manufacturing, marketing and distribution of pharmaceuticals affects the assessment of whether the parties are actual or potential competitors on the Italian market. For instance, having (or having applied for) authorisation to sell certain drugs in Italy may be enough for the ICA to conclude that the parties' activities overlap on national markets. Similarly, the ICA will assess whether a manufacturer has entered advanced clinical trial stages (eg, phase 2 or 3) to assess potential competition issues. Furthermore, the ICA may look into how a concentration may negatively affect the availability in Italy of a sufficient variety of products to meet domestic demand.

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

The way the ICA has defined product and geographic markets in the pharmaceutical sector is consistent with the consolidated case law of the European Commission (Commission).

Product market

The ICA looks at the anatomical therapeutic classification (ATC) of the drug to assess the therapeutic usage. Normally, drugs classified under the same group at the narrowest ATC level (ie, usually at ATC4, though sometimes also at ATC3) are deemed to be substitutable and thus belong to the same relevant product market. Drugs classified under the same group at upper ATC levels (eg, ATC1, 2 or 3) may not be deemed sufficiently substitutable and, therefore, do not necessarily belong to the same relevant product markets (see, eg, case C8880 of 15 November 2007, *Amgen/Dompé Biotec*). However, certain products (eg, cosmetics, or multipurpose drugs) may, nonetheless, be included in the same product market despite being classified under different groups at ATC4. That may depend, variably, on specific features of the supply and demand structures. For instance, in case C11488 of 22 February 2012 (*Lauro Quarantotto/Euticals*), when dealing with cosmetics and nutrition products the ICA identified the product market without resorting to ATC classification.

Geographic market

The ICA has constantly defined the markets for manufacturing and commercialisation of pharmaceuticals as national in scope on the grounds that there still exist significant differences between national policies and regulations on, for example, prices, reimbursement terms, drugs classification, distribution channels and market-access regimes between EU member states. However, when dealing with certain types of products that serve more general needs (eg, cosmetics), the ICA has defined the geographic market as supranational in scope (or at least EEA-wide) in consideration of the significant cross-border commerce enumerated for such products, the absence of significant administrative or technical barriers, homogeneity of pricing and reduced incidence of transports costs (case C11876 of 16 January 2013, *SEPPIC/Biotechmarine*). Further, the market for future products (ie, in clinical trial phases 1 or 2) and for R&D in the pharmaceutical sector has been considered likely worldwide (or at least EU-wide) by the ICA (see, among others, case C10665 of 21 July 2010, *Aptuit/GlaxoSmithKline* and C8880). On the contrary, the ICA has defined the distribution markets of pharmaceuticals as of sub-national dimension in regard to the homogeneity of demand and supply features at regional level (Case C11954 of 7 August 2014, *Cooperativa Esercenti Farmacia/CO.FA.PI*).

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

Consistently with EU merger case law and applicable guidelines, the ICA must assess potential efficiencies generated by a transaction that have been substantiated by the parties in the course of the proceedings. In principle, the strengthening of R&D capabilities at national level might be critical to clear certain concentrations that would otherwise be deemed problematic for competition, provided that a similar outcome would be unlikely to be attained absent the concentration.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

The ICA will follow the Commission's guidelines on the assessment of horizontal mergers to this purpose. Hence, it will rarely open a Phase II investigation if the parties' combined market share does not exceed 30 per cent; or if the increase in the parties' market share as a result of the transaction is not appreciable (ie, less than 1 per cent).

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

Conversely (see question 13), a concentration might be deemed problematic by the ICA if the parties' combined market share exceeds 30 per cent (though competition concerns are more likely to arise when it is approaching 40 per cent).

Potential competition is assessed by evaluating the parties' products in the clinical trial phase (normally only phases 2 or 3 are relevant, eg, Case C10539 of 22 April 2010, *Eli Lilly/Boehringer Ingelheim International*) or awaiting marketing authorisation. The overall R&D activities and pipeline of projects (even before the clinical trials stage) may also play a role in the overall assessment of potential competition.

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

The ICA follows the Commission's guidelines and case law to assess mergers and identify adequate remedies. Hence, the ICA normally

favours structural or quasi-structural remedies (eg, divestments, mandatory licensing or third-party access to production lines) over behavioural remedies (eg, commitments not to exceed certain pricing ranges or to raise barriers to competitors), which are rarely deemed sufficient by themselves.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

Yes – consistently with the Commission's Consolidated Jurisdictional Notice (section 24), the acquisition of patents, brands, or licences may constitute a concentration, as long as such assets constitute a business to which a market turnover is clearly attributable (see, eg, case C10539).

Anticompetitive agreements

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

The combined provision of articles 2 and 4 of Law 287/90 mirrors the content of article 101 TFEU. Also, pursuant to article 1.4 of the same law, the ICA must apply national competition law in conformity with EU law and principles. Hence, there is no material difference on how the ICA interprets and applies the relevant provisions.

18 To what extent are technology licensing agreements considered anticompetitive?

There is no specific national rule or case law concerning technology licensing agreements that may affect the direct application of the EU Technology Transfer Block Exemption Regulation (TTBER) and of the related Commission guidelines. No material difference is expected in the application or interpretation of the relevant rules and principles by the ICA or by national courts.

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

The Code of Pharmaceuticals expressly provides that the MAH can enter into agreements with other pharmaceutical companies for the co-promotion or co-marketing of pharmaceuticals towards professional operators (article 119.5).

Nonetheless, the ICA assesses co-promotion and co-marketing agreements under the general principles and criteria laid down in the Commission's guidelines on vertical or horizontal cooperation. In particular, a co-promotion or co-marketing agreement that has as its object or effect the coordination of the competitive behaviour of the parties, in a way that appreciably reduces competition on prices, quality or innovation, may be prohibited and sanctioned by the ICA.

For example, in case I770 of 4 June 2015 (*Arca/Novartis-Italfarmaco*) the ICA maintained that a co-marketing agreement that the parties: exchange sensitive information on their future commercial strategies and activities (particularly on the envisaged amount and frequency of orders); subject one party's commercial and investment policies to the other party's pervasive supervision; or impose on one party to achieve a minimum market share and to report it to the other party for monitoring purposes, may have the effect of restricting competition and must, therefore, be amended to make it more adequate and proportionate to attain legitimate business objectives (eg, stimulating investments, and allowing the licensor to efficiently plan and allocate resources to the contract products as well as to monitor compliance by the licensee with applicable laws and regulation).

However, in the same case (which was closed with commitments) the ICA stated that a non-competition clause between the parties could be justified by the need to prevent the licensee or distributor from free-riding on the licensor's investments by directly distributing competing products. In general, a degree of reduction of competition between the parties of similar agreements is deemed necessary and strictly related (ie, ancillary) to the legitimate objective of the agreement (see also cases C8880 and C10539).

Co-marketing or promotion agreements between originators and generics may also be carefully scrutinised by the ICA to assess whether they entail a pay-for-delay or reverse payment scheme in light of the *Lundbeck* case (COMP/AT39226).

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

The ICA is prone to pursue anticompetitive agreements in the sector, all the more where they occur in the context of supply of reimbursable drugs to the NHS or in relation with public tenders (I639 of 26 April 2006 – Disinfectants; I770 and case I792 of 21 December 2016 – tenders for oxygen and ventilation therapies). A contractual obligation to distribute products exclusively through certain channels may also be problematic in certain cases (eg, only through pharmacies for non-prescription drugs).

Further, the ICA seems amenable to sanction the exploitative misuse of regulation or patent disputes to justify restrictive agreements, settlements or concerted practices between pharmaceutical companies. In case I760 of 27 February 2014 (*Roche-Novartis/Farmaci Avastin and Lucentis*) the ICA found that the parties infringed article 101 TFEU by entering into a licensing and co-distribution agreement for potentially competing drugs, which, allegedly, had been artificially differentiated based on a speculative interpretation of the regulation on the off-label use of drugs with a view to sharing monopolistic profits.

Confidentiality provisions or agreements are not always adequate or sufficient to remove competition concerns.

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

The ICA will investigate vertical agreements between pharmaceutical companies in accordance with the framework set out by the Commission's Vertical Block Exemption Regulation and the related guidelines and case law. However, it is worth mentioning that the ICA has proved more prone to investigate vertical agreements in the pharmaceutical sector than in other industrial sectors, where such agreements have been rarely scrutinised. See questions 19 and 20.

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

That requires a case-by-case analysis. The ICA will assess agreements to settle patent disputes between pharmaceutical companies in conformity with the framework set out by the TTBER and the related Commission's guidelines and case law. The final report of 8 July 2009 of the Commission's sector enquiry in the pharmaceutical sector as well as the *Lundbeck* case (as reviewed by the CJEU) set the standard for the ICA's approach to, and evaluation of, such settlement agreements under article 101 TFEU.

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

The most recent sector inquiry of the ICA on human vaccines identified several information asymmetries between manufacturers and buyers (either the NHS or private buyers), which are deemed problematic for competition in the relevant market. Lack of transparency, rather than too much transparency, was seen as problematic with respect to, inter alia, the prices and data required to assess the viability and essentiality of certain vaccines compared to others (see question 8). However, this concern may not apply to all pharmaceutical markets.

Anticompetitive unilateral conduct

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

In Italy, the prohibition to abuse of a dominant position is set forth in article 3 of Law 287/90, which reflects the content of article 102 TFEU. There is no reportable difference on how the ICA (or the national courts) and the Commission (or the EU courts) interpret and apply the substantive provisions on abuse of dominance in the sector.

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

Similarly, to this end the ICA, as well as the national courts, make use of the criteria set out in the Commission's Guidance on abusive

Update and trends

Over the past three years the ICA has increased its investigative activity and fining policy against anticompetitive agreements and abuses of dominance. In particular, the public tender sector seems targeted by the ICA. The pharmaceutical sector will, therefore, certainly experience continuing or increasing scrutiny by the ICA.

The stance taken by the Commission against excessive pricing practices in the pharmaceutical sector and its innovation-enhancing policy further support the idea of the ICA increasing enforcement activity. On 19 January 2017, the ICA and AIFA entered into a public cooperation agreement setting out a protocol to exchange information on ongoing investigations or information relevant to their respective institutional tasks in order to foster each other's monitoring and enforcement activity. They have also committed to conduct joint studies and initiatives on how to improve competition in the sector. The NHS is also willing to take advantage of the facilitation provided by the Antitrust Damages Directive, which in turn stimulates the ICA's enforcement activity.

In addition, considering the concerns for competition identified by the ICA in relation with the market for human vaccines at the outcome of the sector inquiry (see question 8), we may expect regulatory interventions to fill certain regulatory gaps and information asymmetries, which, according to the ICA, have allowed vaccine manufacturers to exploit their market power and increase prices to the NHS as well as to private buyers.

A final decision of the Council of State on the appeal against the ICA's decision in case I760 (*Avastin/Lucentis*) is expected in 2017–2018. The Council of State will have to wait for the CJEU to render its judgment in the preliminary reference on certain questions relating to whether the parties of a licensing agreements may be deemed competitors where the licensee is only active on the relevant market because of the licensing agreement itself; and on how marketing authorisations or off-label use of pharmaceutical products may affect the definition of the relevant market.

Finally, a draft law aimed at increasing competition in certain sectors, including the distribution of pharmaceuticals, is under discussion at the Italian parliament. The text of the draft law is very fluid as it has been subject to continuing debate and changes in the past few years without being approved so far.

exclusionary conduct by dominant undertakings and in the CJEU's case law. There are no reportable divergences in the pharmaceutical sector.

Consistently with the Commission's approach, an undertaking with a market share below 40 per cent is very unlikely to be considered dominant. However, the ICA will assess further features of the market structure (demand and supply elasticity, potential competition, barriers to entry, technological developments, timescale for market entry of generics, etc) to assess dominance (case A431 of 11 January 2012, *Ratiopharm/Pfizer*; and A480 of 26 September 2016, *Price increase of Aspen's Pharmaceuticals*). One cannot rule out that, in certain circumstances, an undertaking with a market share between 30 per cent and 40 per cent might be considered dominant in the light of peculiar market features that, for instance, make the existing competitors likely to exit the market in the short or medium term or incapable of competing effectively because of their atomisation.

To assess joint or collective dominance, the ICA as well as national courts apply the same criteria set out in the Commission's and EU courts' landmark cases (namely ECJ, case C-396/96, *Compagnie Maritime Belge/Commission*; and case T-342/09, *Airtours/Commission*). In case C10955 of 16 March 2011 (*Ardagh Glass/FI PAR*), the ICA ruled out the contention that the concentration would have created joint dominance because of a significant countervailing buying power on the demand side and law barriers to entry.

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

Holding a valid patent on a drug is likely to confer dominance to the patent holder only if there are no equivalent therapeutic alternatives that are as efficient as the patented drug for a certain disease. Further, the fact that a patent is expired, or near to expiration, does not rule out dominance if no generic or original alternative for that drug is likely to enter the market in the short term.

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

In line with EU case law, the ICA may find the exploitative misuse of the patent system by a dominant patent holder with a view to exclude, deter or make it more difficult for a competitor to enter the market abusive (abuse of dominance by 'abuse of rights'). For example, in case A431, the ICA fined Pfizer for having requested the extension of the duration of the patent coverage after its natural expiration and threatening legal actions to enforce the exclusivity against generics, thus delaying their market entry. The Italian Council of State confirmed the ICA's decision on 12 February 2014, following the annulment of the ICA's decision by a lower court.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

The ICA should act in accordance with EU case law and principles on this regard.

Life-cycle management strategies do not, by themselves, constitute abuse of dominance if they are performed by genuinely and fairly relying on regulatory provisions aimed at protecting the recovery of initial investments by manufacturer or MAHs. Conversely, any misuse by a dominant manufacturer or MAHs of regulatory provisions, as well as of regulatory gaps, to artificially extend market or data exclusivity protections and resulting in the exclusion or delay of competition may be deemed abusive by the ICA (being the result of an 'abuse' or 'misuse' of rights).

In Case A480 (*Price increase of Aspen's pharmaceuticals*), the ICA has maintained that the way Aspen re-negotiated the price of certain reimbursable drugs with the AIFA (by threatening to delist such drugs to a non-reimbursable (and therefore free-to-market) class) constituted an abuse of dominance in the form of imposing unfair pricing conditions (excessive pricing). The ICA argued that Aspen instrumentally threatened to delist the drugs concerned in order to cut off already scarce supplies to the Italian market, knowing that by doing so it would force the AIFA to accept its unfair pricing terms (the AIFA accepted a price increase of up to 1,500 per cent of the original price).

On 1 March 2017 the ICA opened new proceedings against Aspen alleging the company's failure to comply with the order to cease the abusive conduct and re-negotiate prices on fairer terms.

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

There is no case law in Italy on such conduct, but it will likely be deemed abusive if the effect is to prevent competition that would otherwise have existed. See questions 20, 27 and 28. However, one cannot rule out that it may be objectively justified, or even pro-competitive, depending on the specific circumstances.

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

The objective indispensability of a practice to achieve a public goal related to the protection of health may, in principle, justify certain conducts that would otherwise be deemed contrary to competition law. In addition, a careful interpretation and application of the regulatory framework applicable to the R&D, manufacturing and supply chain may provide objective legal justifications to certain behaviours or conducts.

The huge, long-term investments required to research, trial and market pharmaceuticals are a characteristic feature of this sector. Undertakings need the right incentive and safeguards to tackle the risk and to collect the resources and financing needed to discover new therapies and bring a new drug on the market. Certain life-cycle and patent-related practices or restrictions might also be objectively justified on such grounds, if properly substantiated. The ICA will assess such cases in line with the EU case law (eg, case C-501/06 P of 6 October 2009, *GlaxoSmithKline Services and Others v Commission*).

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

Yes – the ICA has since increased the attention and scrutiny over agreements and practices in the pharmaceutical sector in Italy. As a consequence, the ICA issued a few landmark decisions on competition law infringements in the sector (eg, cases A431, A480 and I760). However, this trend has only clearly emerged in the last four to five years and may increase in future as a result of the findings of the sector inquiry into the marker for human vaccines, and of the ICA's revitalised attention on competition enforcement in the pharmaceutical industry.

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The primary piece of legislation setting out the regulatory framework for the marketing and authorisation of pharmaceutical products is the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (No. 145 of 1960) (the Act), the name of which was changed from the Pharmaceutical Affairs Act as of 27 November 2014.

The Health Insurance Act (No. 70 of 1922) (HIA) sets out the pricing of drugs covered by public health insurance (these drugs are roughly equivalent to drugs used in medical institutions and prescription drugs). Under the Japanese health insurance system, generally all residents of Japan are required to be covered by health insurance, and most of the drugs used in, or prescribed by, medical institutions are covered by this mandatory insurance. Under the health insurance system, the total prices of drugs that medical institutions and dispensing pharmacies charge to insurers (national government or others) and insured persons are calculated according to a notification of the Ministry of Health, Labour and Welfare (MHLW). Prices of over-the-counter (OTC) drugs are not subject to the notification. This chapter focuses primarily on drugs covered by public health insurance.

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

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

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

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

The Act is not directly relevant to the application of competition law to the pharmaceutical sector. Some provisions of the Act regarding regulations on advertising may relate to competition law in a broad sense as they come under consumer protection.

Competition legislation and regulation

4 Which legislation sets out competition law?

The main body of Japanese competition law consists of the Act concerning Prohibition of Private Monopolisation and Maintenance of Fair Trade (No. 54 of 1947) (Antimonopoly Act (AMA)).

The Act against Unjustifiable Premiums and Misleading Representations (No. 134 of 1962) (PRA) governs the area of trade description (such as labelling or advertisement of products). Based on article 3 of the PRA, the Japan Fair Trade Commission (JFTC) has issued a notice on the Restriction on the Provision of Premiums in Medical Drug Business, Medical Equipment Business and Sanitary Survey Business (Notice No. 54 of 1997).

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

The JFTC is the main competition agency in Japan, and it investigates and decides antitrust issues in the pharmaceutical sector, as well as in any other field, unless a criminal case is initiated. In 2009, the Consumer Affairs Agency (CAA) was established to protect the interests of consumers, and is mainly responsible for the enforcement of the PRA.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

The remedies that the JFTC can impose are cease-and-desist orders, and orders for the payment of surcharges (administrative fines). The Secretary General of the CAA can impose cease-and-desist orders on the violation of the PRA, and effective 1 April 2016, the Secretary General of the CAA can also issue orders for the payment of surcharges on certain types of violations of the PRA (see 'Update and trends').

The JFTC also has the authority to request that the Public Prosecutors' Office lay charges, which could lead to criminal sanctions for certain types of antitrust violations, such as hard-core cartels. However, the number of such criminal cases usually does not exceed one per year.

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

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

In addition to the right to claim damages under general tort law (article 709 of the Civil Code), private parties have competition-related remedies under the AMA. One of the remedies is the right to demand injunctions.

If a person is suffering, or likely to be suffering serious harm, as a result of an act that can be characterised as 'unfair trade practices' (which is defined in the AMA and a notification of the JFTC), they can demand the suspension or prevention of the act of violation (AMA, article 24). A typical example is a case of unjust low price sales, where a company can request an injunction because of claims that its competitor's pricing is too low (typically, below cost).

Another remedy under the AMA is the right to claim damages (article 25). This right to claim damages is different from the right to claim damages under general tort law in that the defendant cannot be exempted from the liability to indemnify the plaintiff by proving that there exists no wilfulness or negligence on their part. However, in order to claim damages based on this right, the cease-and-desist order or the order for payment of surcharges must have become final and conclusive before the plaintiff claims the right (AMA, article 26).

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

Although there is no specific provision in the AMA, it is interpreted in such a way that the JFTC may conduct necessary inquiries, including

sector-wide inquiries, provided addressees of such inquires voluntarily respond to them. In 2015, the JFTC and Competition Policy Research Center (an arm of the JFTC dedicated to research and study) jointly conducted inquiries on competition in the pharmaceutical sector, with a particular focus on generic drugs. The JFTC conducted a number of interviews with pharmaceutical companies operating in Japan during the project. In their final report issued in 2015, they concluded that while the market structure in Japan makes it less likely for 'reverse payment' settlements to be prevalent, the JFTC should monitor the market practices continuously.

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

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

There are a number of non-government groups relating to the pharmaceutical sector. Although their petitions or opinions do not primarily focus on antitrust issues, they may have some impact on antitrust policy in the pharmaceutical sector. They include the Japan Generic Medicines Association (JGA) and the Japan Pharmaceutical Manufacturers Association (JPMA). In relation to this, on 21 January 2015, the Kyoto District Court ordered the enjoinment of certain forms of representation and distribution of advertisements of chlorella products by a seller of health foods by holding that, in seeing the representation, consumers are likely to misunderstand that the product has been approved as medicine under the Act, which is not the case in reality. However, the Osaka High Court overturned it on 25 February 2016 as the defendant had already ceased the advertisements, and this was ultimately supported by the Supreme Court on 24 January 2017. This case was initiated by a consumer organisation that is not focused on the pharmaceutical sector, but rather on general consumer affairs.

Review of mergers

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

Like other mergers, the merging of two pharmaceutical companies is reviewed according to the substantive test of whether the merger 'may be substantially to restrain competition in any particular field of trade'.

In a merger review, the JFTC used to characterise the market of prescription drugs as an industry where the competitive pressure from the downstream market was intense. That is to say, the JFTC stated that with regard to medical drugs, customers of pharmaceutical companies (ie, wholesalers and medical institutions) had been conducting a variety of efforts to procure less expensive products, and competition among wholesalers for medical institutions was high (*Sankyo/Daiichi*, 2005; *Yamanouchi/Fujisawa*, 2005). We believe that this feature of intense competitive pressure from the downstream market contributed to the JFTC's greenlighting of these mergers.

However, in another more recent case, the JFTC stated that competitive pressure from the downstream market to the prescription drug market was not intense, because patients had little control over which drugs their doctors would prescribe to them, and doctors had little incentive to prescribe more affordable drugs to patients, since patients pay the cost of prescription drugs (*Kirin Holdings/Kyowa Hakko*, 2008). This may indicate the change of the JFTC's recognition of the features of the prescription drug market.

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

In both the *Sankyo/Daiichi* and *Yamanouchi/Fujisawa* merger cases (see question 10), the JFTC defined the product market of medical drugs in light of the anatomical therapeutic chemical classification (ATC) code developed by the European Pharmaceutical Marketing Research Association. The ATC code classifies medical drugs in accordance with the main drug efficacy of the main ingredients. While there are four levels of classification in the ATC code, from level 1 to level 4 (level 4 is the most detailed classification), the JFTC noted that the product market of medical drugs should generally be defined in accordance with the level 3 classification. While this is the basic method of defining the product market, the JFTC also considers substitutability from the viewpoint of medical institutions. The *Novartis/GlaxoSmithKline* case of fiscal year 2014 defined such product markets based upon level 4 classification and independently from the ATC code.

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

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

It is unlikely that calling for the strengthening of research and development activities in Japan would be useful in alleviating antitrust concerns. While the Guidelines to Application of the Antimonopoly Act Concerning Review of Business Combination of the JFTC, which were most recently amended effective as of 1 July 2011 (the Merger Guidelines), refers to efficiency as one of the factors, because the improvement of efficiency must be specific to the merger (ie, should not be one that can be achieved by another method), we are unaware of any merger cases in which efficiency singularly plays a significant role in obtaining clearance.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

A product and geographical overlap between two merging parties will be problematic, if the merger 'may be substantially to restrain competition in any particular field of trade'. 'Competition' here includes both actual and potential competition (AMA, article 2(4)). Once the Tokyo High Court held that 'substantially to restrain competition' means that because of reduced competition, a particular company or a group of particular companies brings a situation where it can dominate a market by setting, at its own will and freely to some extent, prices, qualities, quantities and other conditions (*In re Toho and Shin-Toho*, Tokyo High Court judgment, 7 December 1953).

The Merger Guidelines provide more detailed guidelines to the review of horizontal mergers. According to the Merger Guidelines, when relevant products are characterised to be differentiated by brands, etc, the merger will be problematic if parties to a merger sell products highly substitutable for each other and other competitors' products are not so highly substitutable to the products of the parties to the merger, because the parties could increase the price of the product without losing many sales after the merger. Even when relevant products are characterised to be homogeneous, a merger of competitors will be problematic if other competitors cannot increase their output because of their limited production capacity or for other reasons.

On the other hand, the Merger Guidelines set forth the following safe harbour rules. Horizontal mergers will not be considered problematic if:

- the Herfindahl-Hirschman Index (HHI) after the merger is not more than 1,500;
- the HHI after the merger is over 1,500 but not more than 2,500, while the increment of HHI does not exceed 250; or
- the HHI after the merger is over 2,500, while the increment of HHI does not exceed 150.

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

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

When product X that is being developed by a party to a merger is, if launched, expected to become an influential competing product with existing product Y of another party to the merger, and the launch of the product X is likely, such overlap between the products X and Y may be problematic. In the *Kirin Holdings/Kyowa Hakko* case of 2008 (see question 10), the JFTC cited such overlap involving products under development as one of the reasons why the merger between the parties should come with a remedy. Further, in the *Novartis/GlaxoSmithKline* case (see

question 11), the JFTC analysed that there was an overlap involving two products to be launched in the near future of one party and two products during Phase III clinical trials of the other party.

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

In the area of merger control, the most typical remedies would require the parties to a merger to divest themselves of overlapping products or assets. Other typical remedies include: allowing competitors access to bottlenecking facilities owned by the parties; providing competitors with technological assistance; and granting competitors or customers with the right to procure overlapping products on a production-cost basis.

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

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

Mere acquisition of one or more patents or licences will not be subject to merger reporting under the AMA.

Anticompetitive agreements

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

In general, the AMA prohibits three types of activities:

- private monopolisation (activities to exclude or control the business activities of other entrepreneurs);
- unreasonable restraint of trade (activities to restrict or conduct business activities mutually with other entrepreneurs in such a manner as to fix, maintain or increase prices, limit production or products, or other similar matters); and
- unfair trade practices (activities stipulated by the AMA or designated by the JFTC as activities that unjustly discriminate against other entrepreneurs, deal at unjust prices, deal with another party on such terms as will unjustly restrict the business activities of the other party, and other similar practices).

It should be noted that, under the AMA, while private monopolisation and unreasonable restraint of trade require the level of restriction on competition to be substantial, a tendency to impede competition would be sufficient for the purpose of unfair trade practices (see also question 24). It can be said that private monopolisation corresponds approximately to the abuse of dominant position under EU competition law, and unreasonable restraint of trade includes almost all illegal cartels.

18 To what extent are technology licensing agreements considered anticompetitive?

The Guidelines for the Use of Intellectual Property under the Antimonopoly Act issued by the JFTC on 28 September 2007 (the IP Guidelines; most recently amended on 21 January 2016) set out to what extent technology licensing agreements are considered to be anticompetitive. Examples of agreements ancillary to technology licence agreements that are in principle considered to be anticompetitive are those that:

- prohibit a licensee from research and development of the licensed technology or competing technologies;
- oblige a licensee to assign improved technology, or grant an exclusive licence for that technology back to a licensor; or
- oblige a licensee to sell products utilising a licensed technology at a price designated by a licensor.

The IP Guidelines further cite, as examples of less but still potentially anticompetitive ancillary agreements, agreements that are considered anticompetitive to the extent that their effect may be to impede fair competition that:

- restrict a licensee from using licensed technology even after the expiration of the patent right to the licensed technology;
- oblige a licensee, beyond the necessary extent, to procure raw materials, etc, necessary to use licensed technology, only from suppliers designated by a licensor;
- prohibit a licensee from selling products using licensed technology to persons other than those who are designated by a licensor;
- prohibit a licensee from selling or manufacturing competing products; or
- oblige a licensee to pay an amount of royalties, which is not calculated according to the use of licensed technology.

On the other hand, according to the IP Guidelines, in principle, it is not considered as unfair trade practices for a licensor to:

- restrict the purpose of a licence (such as a licence only for either domestic sales or export);
- restrict the period of a licence;
- restrict the location of production; or
- set a minimum requirement in relation to the amount of production.

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

The anticompetitive effect of co-promotion and co-marketing agreements will be evaluated on the basis of a rule of reason. These agreements can be pro-competitive, because they can reduce transaction cost or result in improved economies of scale. This is particularly true where promotion or marketing by one of the firms involved is too risky and the relevant pharmaceutical products cannot be sold in Japan without co-promotion or co-marketing. On the other hand, such agreements may be considered anticompetitive, because they are in most cases agreements among competitors and may reduce competition between the parties to some extent.

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

In 1975, the JFTC issued a cease-and-desist order against eight manufacturers of a live vaccine made to protect pigs from hog cholera to renounce an agreement to supply the vaccine only to an association that the manufacturers established, as well as an agreement on the assignment of production among them.

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

An agreement with a competitor is most likely to be deemed anticompetitive if it is characterised as a hard-core cartel. On the other hand, a joint venture can be pro-competitive and is generally evaluated on the basis of the rule of reason.

The JFTC stated in 2004, in response to a consultation request, that it was not against the AMA for two pharmaceutical companies to establish a joint distribution department (or channel) for medical drugs. This was as long as the exchange of information was blocked by a firewall and the competition between the manufacturing and sales departments of these pharmaceutical companies survived the establishment of the joint distribution department. The JFTC did admit that if each company had access to information regarding the sales of the other company, such access could be used to avoid competition.

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

Vertical agreements are typically categorised as unfair trade practices among the three types of violations under the AMA. In the pharmaceutical sector, resale price maintenance, one of the unfair trade practices, would most frequently raise antitrust concerns.

In 1991, the JFTC ordered Eisai Co Ltd, one of the leading pharmaceutical companies in Japan, to withdraw its directions to retailers that Eisai's vitamin E products be sold at the retail price stipulated by

Update and trends

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

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

Eisai and that retailers should not resell the vitamin E products to other retailers, as it held that these directions constituted 'unfair trade practices'. The JFTC further prohibited Eisai from:

- investigating the status of the resale price maintenance and resale from a retailer to other retailers by trial purchases;
- tracking the channels of resale of products to other retailers by placing hidden lot numbers on the products; and
- placing the name and telephone numbers of retailers on products they deal with.

The JFTC also ordered Eisai to make its corrective actions, as listed above, known to retailers and consumers.

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

There has not been any case where the settlement of a patent dispute was challenged as an antitrust violation. There are no guidelines for the settlement of a patent dispute and an antitrust violation either. However, theoretically speaking, if competitors reach a settlement of a patent dispute and the settlement includes provisions that substantially restrain competition in a particular field of trade, the competitors will be held liable for an unreasonable restraint of trade (see question 17). The JFTC published 'Competition in the Pharmaceutical Market and Incentives for Research and Development – through Review of Effects of Entry of Generic Drugs into the Market' on 7 October 2015, alerting pharmaceutical companies in Japan to the issue of reverse payments, and is believed to be continuously monitoring market practices with interest (see question 8).

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

Consistent with similar initiatives in other jurisdictions, a number of trade associations (including the JGA and the JPMA (see question 9)) have published guidelines on transparency with regard to the relationship between pharmaceutical companies and medical institutions. Similarly, certain information on ongoing clinical trials is available at various sources, including the MHLW website. However, we are unaware of any influential arguments that such initiatives for transparency have increased the likelihood of anticompetitive exchanges of information. Please note that conscious parallelism is not a violation of the AMA.

Anticompetitive unilateral conduct

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

The AMA does not require a firm to have a monopoly or a certain level of market power for it to be held liable under private monopolisation. That said, because the restraint has to be 'substantial' for the purpose of private monopolisation, it is considered that market share of the violator (or combined market share of the violators) shall be substantially large in a particular field of trade (see question 25). There are two types of conduct that may be deemed private monopolisation: exclusion of competitors and controlling of competitors. To the extent that a firm excludes or controls the business activities of other firms and causes a substantial restraint of competition in any relevant market, the conduct of this exclusion or control will be considered to be private monopolisation and therefore against the AMA.

Anticompetitive unilateral conduct can also be recognised as constituting 'unfair trade practices', as long as this conduct falls within one of the categories stipulated by the AMA or designated by the JFTC. Under unfair trade practices, a firm will be held liable if it commits one of these activities and the activity tends to impede fair competition (see question 17).

It is generally thought that a 'substantial restraint of trade' (the standard under private monopolisation) requires a higher degree of anticompetitiveness than the 'tendency to impede fair competition' (the standard under unfair trade practices). Because most activities of private monopolisation overlap with those of unfair trade practices, private monopolisation (because of its higher standard of anticompetitiveness than unfair trade practices) has only been enforced in a very limited number of cases.

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

There is no definition of 'dominant' or 'jointly dominant' under the AMA. The meaning of the term 'dominant' may be different depending on the context in which the term is used, and the consequence of a firm being considered dominant is not clear. Nonetheless, the Guidelines for Exclusionary Private Monopolisation under the Antimonopoly Act, issued by the JFTC on 28 October 2009, state that the JFTC, when deciding whether to investigate a case as Exclusionary Private Monopolisation, will prioritise the case, among others, where the market share of a firm exceeds approximately 50 per cent. Thus, as a rule of thumb, a firm with market share of more than 50 per cent will likely be considered dominant in the context of exclusionary or control types of private monopolisation and should use more caution than other companies.

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

No, a patent holder cannot be generally dominant simply because it holds the patent. In Japan, the relevant market tends to be defined broadly compared to in the US or the EU, so the mere holding of patent rights generally would be unlikely to lead to a dominant position.

However, the IP Guidelines state that if certain technology is used by many competitors in a certain industry and it is difficult for them to develop circumventing technology or to switch to other technology, then that relevant technology may be defined as the market. In such an exceptional case, a patent holder could be held dominant largely because of the patent it holds.

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

There has not been any case where a patent owner was held liable for an antitrust violation because of the application for patent.

In the area of trademark application, there has been a case of abuse of trademark applications where a dominant local newspaper company filed applications, in order to solely prevent a new entry and with no intention to use, for nine trademarks relating to the name of local newspapers to be used in the same region. Although the dominant local newspaper company withdrew all applications, in 2000 the JFTC issued a recommendation decision (which is similar to a

consent decree) to prevent it from engaging in the same type of activity, because these activities were a part of exclusionary conduct that fell under private monopolisation (*In re Hokkaido Shimbun*). However, in the area of patent applications, such arguments would be quite difficult because the filing of applications for patent can seldom be exclusionary as opposed to filings for trademarks, no matter how many applications are filed.

The IP Guidelines do not suggest such a possibility either, even though they state that acquisition of technology used by competitors, followed by refusal to license, or collection of technology by competitors without any intention to use them, as well as exercising certain facets of a standard essential patent (like seeking an injunction against those who are willing to obtain a licence after FRAND declaration), could violate the AMA.

Article 21 of the AMA stipulates that the provisions of the AMA shall not apply to acts recognisable as the enforcement of a patent. However, it is generally interpreted that the enforcement of a patent cannot be without limitation and the AMA should apply even to the enforcement of a patent. The IP Guidelines stipulate that any business activity that may seemingly be an enforcement of a right cannot be 'recognisable as the enforcement of the rights' under article 21, provided that it is found to deviate from or run counter to the purposes of the intellectual property system, which is namely to motivate firms to realise their creative efforts and make use of technology, in view of the purpose and manner of the conduct and the scale of its impact on competition.

The IP Guidelines state that, in principle, it will not raise anticompetitive concerns for a rightholder of a technology to refuse licensing his or her technology, which is typically deemed as the enforcement of a patent. However, the IP Guidelines provide exceptional cases that may raise anticompetitive concerns, including where:

- companies participating in a patent pool agree to refuse to grant a licence to new entrants;
- a firm obtains from a rightholder a right to an influential technology that is used by many other firms in the same industry, and then refuses to license to other firms; and
- a firm collects all rights to technology that may be used by competitors without any intention of using them, and then refuses to issue a licence.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

The JFTC has never raised an issue of life-cycle management strategies in regard to an antitrust violation.

Historically, brand-name pharmaceutical companies used to sue generic pharmaceutical companies in order to delay the entry of a generic drug, on the grounds that conducting tests necessary for an application of product-specific approval, under article 14 of the then-current Act during the effective term of the right to a patent that is used in the generic drug, is patent infringement. However, in 1999 the Supreme Court put an end to the argument by holding that such testing would fall under 'working of the patented invention for experimental or research purposes' and thus not be considered an infringement of patent rights.

Following this decision of the Supreme Court, it is said that brand-name pharmaceutical companies are trying to delay the entry of generic drugs in another way (ie, on the grounds that there is an infringement of patents related to the manufacturing method, whose application was filed later than the one for substance patent).

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

Yes, it is possible. The first 'authorised generic' in Japan was launched in 2013. Such practice is not commonly seen in Japan, because the launch of an authorised generic generally results in a considerable decrease in the price of drugs calculated according to a notification of the MHLW (see question 1), which has the effect of pushing down the prices at which drug manufacturers sell their drugs.

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

There has not been any case reported in which courts or the JFTC took the specific features of the pharmaceutical sector into account when examining an antitrust issue. However, in a case referred to in question 20, the JFTC accepted the parties' statement that the medical drugs at issue had to be able to be supplied in a prompt and stable manner, even in cases of large-scale natural disasters. In this case, the JFTC might have implicitly taken the specific features of the pharmaceutical sector into account. It is difficult for the specific features of the pharmaceutical sector to provide an objective justification for hard-core cartels, but they could be taken into consideration to a certain extent, especially in the cases of certain categories of collaboration among competitors and vertical restraints (those that are subject to rule-of-reason review) and merger clearances.

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

Not applicable.

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

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

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

The Ministry of Food and Drug Safety (MFDS, formerly known as the Korea Food and Drug Administration) and the Ministry of Health and Welfare (MoHW) each enforces select provisions of the PAL; the MoHW enforces the NHIA and the Korea Fair Trade Commission (KFTC) enforces the FTL. The Prosecutor's Office and the police generally enforce the Korean Criminal Code, as well as the criminal provisions of the PAL, NHIA and the FTL.

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

The PAL is also the statute that governs the distribution of pharmaceuticals and prescribes licensing, facilities and other requirements for wholesalers and pharmacies.

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

The FTL is the principal body of competition law in Korea, which is relevant for all sectors of industry, including the pharmaceutical sector.

Competition legislation and regulation

4 Which legislation sets out competition law?

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

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

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

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

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

If the KFTC determines that there is a violation of the FTL, it may:

- issue a corrective order demanding that the offending party or parties immediately cease all prohibited activity;
- require publication of a formal announcement of the violation in accordance with specifications; or
- require payment of administrative fines. For serious violations, the KFTC may refer the case to the prosecutors for criminal investigation and possible indictment. These sanctions apply to all violations, regardless of the industry.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

In principle, depending on the type of violation, private remedies are available under the FTL for parties who suffer harm from anticompetitive conduct or agreements, regardless of industry, in the form of injunctive relief or compensatory damages. However, such remedies are limited to compensatory damages to the extent of the actual damages caused by the violating conduct, as Korean courts do not recognise the concept of punitive damages generally. Injured private parties tend to seek recourse by filing complaints with the KFTC, rather than by initiating individual lawsuits against the offending party or parties due to the difficulty in proving the illegality of the conduct, causation and amount of damages.

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

The KFTC may conduct sector-wide inquiries at its discretion and has conducted sector-wide investigations every few years into possible antitrust or fair-trade law violations, focusing primarily on whether pharmaceutical companies are engaged in promotional or marketing activities that constitute unfair solicitation of business. The most recent sector-wide investigation into fair-trade law violations started in October 2006, with the KFTC deciding on the first group of 10 companies investigated (mostly domestic) issued in November 2007 and on the second group of seven companies (mostly multinational) on January 2009. In the first group, all of the companies were subject to administrative fines and five of them were referred to the prosecutors for criminal investigation, which resulted in a finding of violation. As to the second group, all were subject to administrative fines but none was referred to the prosecutors for criminal investigation. The KFTC initiated yet another round of investigations in March 2009 with a finding of FTL violations being made September 2011, against mostly European pharmaceutical companies. No criminal referrals were made.

The KFTC also initiated an industry-wide investigation into intellectual property rights abuse (IPR investigation) in June 2010, with an initial survey of numerous innovator and generic pharmaceutical companies (30 multinational companies and 18 domestic companies), which was the evidence-gathering phase of the IPR investigation. The KFTC followed up in late 2010 and in 2011 with on-site investigations of

a number of companies based on the responses to the initial survey. The KFTC IPR investigation is focused on whether innovators have abused their legally protected intellectual property rights by extending beyond the protected scope of such rights, which would ultimately result in delays in generic entry and, in turn, translate into higher prices for consumers and a burden on health budgets. One investigation was concluded in late 2011, with a finding by the KFTC that a multinational company (an original drug company) and a domestic company (a generic drug company) had entered into a pay-for-delay settlement agreement resolving a patent dispute under which a generic product was withheld from the relevant market and, in turn, consumers. Notably, the KFTC also found that non-compete provisions in exclusive distribution agreements went beyond the exclusionary scope of the underlying patent in the subject case (confirmed by the Supreme Court).

As an extension of the interest in IPR abuse, the KFTC conducted a trademark survey between March and April 2013 that involved a few pharmaceutical companies. The trademark survey, however, was not limited to the pharmaceutical industry but covered various other industries. The trademark survey appears to have been prompted by cases involving alleged unfair trade practices with respect to trademark rights with local small and medium-sized domestic businesses. There has been no follow-on action by the KFTC to date.

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

There are several NGOs and trade associations that address competition concerns relating to the pharmaceutical sector, such as the Korea Pharmaceutical Manufacturers Association and the Korean Research-based Pharmaceutical Industry Association (KRPIA), but their concerns relate more to unfair trade practices than to other areas of competition law, such as cartel, market-dominant position and mergers. There are also consumer rights' groups and patient groups whose focus does not include antitrust concerns per se but whose work in the areas of public health and consumer rights' advocacy may raise or impact on antitrust issues.

Review of mergers

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

The sector-specific features of the pharmaceutical industry – in particular the high degree of regulation as to entry of new products and rules for determining and adjusting the reimbursement prices of drugs – figure prominently in the KFTC's review of merger applications. To assess whether a merger is likely to have an anticompetitive effect, the KFTC first defines the relevant product market and geographic market and then reviews the market shares of the parties and other competitors, the historical trend of the market shares and such other factors as the possibility of new market entry, including imports, the existence of substitutes for the products of the companies undergoing a merger, and the possibility of collusion among competing companies after the merger. The KFTC examines the sector-specific features of the pharmaceutical industry to the extent that they heavily affect the analysis of the above factors. While the KFTC is aware of the contention from the industry that business combination is not necessarily anticompetitive thanks to factors such as substitute products or the price limit regulation, it appears that the reviewing authorities tend to apply a less flexible standard.

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

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

In principle, the product market and geographic market are defined under FTL regulations as the market where a hypothetical monopolist can increase the price by small but significant non-transitory increase in price without losing profit. In practice, the KFTC tends to determine the product market by referring first to the third level of classification (chemical and pharmacological subgroup), also referred to as ATC3 under the anatomical therapeutic chemical (ATC) classification system.

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

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

The FTL recognises that efficiency gains from certain business combinations (eg, efficiency increases in production, sales and R&D efforts or overall efficiency gains in nationwide economy) can be greater than anticompetitive effects. The authorities may allow such collaborative activities under exceptional circumstances where an efficiency-enhancing integration may promote further competition.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

The presumption of anticompetitive effect will arise if the following conditions are met:

- either the combined company holds 50 per cent or more of the market share, or the top three companies (with the combined company as one of them) hold 75 per cent or more of the market share;
- the combined market share is the largest in the market; and
- the combined market share exceeds that of the second market shareholder by no less than 25 per cent of the combined market share.

If the above conditions are met in any product category (usually defined at the ATC3 level), the presumption of anticompetitive effect will arise and the burden will be on the applicants to rebut this presumption (ie, show that the proposed merger is not, in fact, anticompetitive).

Pursuant to an amendment to merger review guidelines, the Herfindahl–Hirschman Index (HHI) analysis may be used to support the presumption of no anticompetitive effect. For this purpose, a presumption of no anticompetitive effect can be asserted in the case of a horizontal merger if:

- the HHI is lower than 1,200;
- the HHI is 1,200 or higher and lower than 2,500 and the increment in the HHI increased by the proposed merger is lower than 250; or
- the HHI is 2,500 or higher and the increment in the HHI increased by the proposed merger is lower than 150.

In a recent merger between two multinational pharmaceutical companies, the KFTC decided the horizontal overlap in one product market was significant enough to restrict competition (the combined market share in the relevant product market was 70–80 per cent) and rendered a decision to impose corrective measures that acquirer sell the assets and rights related to the product to be transferred from the seller to a third party.

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

In general, the KFTC has not tended to consider pipeline products that have not yet reached the stage of Phase III clinical trials in its examination and review of pharmaceutical mergers. Those products that are already in Phase III clinical trials or beyond have tended to be considered together with products that are already on the market to determine whether a proposed merger is likely to be anticompetitive.

The KFTC may factor pipeline products of one merging party likely to compete with the other party's pipeline or existing products into its assessment. Where one or both merging parties have a substantial market share, it may decide that the merger would increase the merging parties' market power with the pipeline products.

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

In general, when the KFTC determines that there are issues with a particular merger, it may decline to approve the merger altogether, or alternatively issue conditional approval requiring, for example, the spinning off of a part of the business of the combined company, a cap on market share or the sale of specific assets. Where the KFTC determines that a merger between pharmaceutical companies may be anticompetitive as

to one or more product categories, the KFTC is likely to order the sale of the products, and the sale would relate only to the Korean market.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

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

Anticompetitive agreements

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

As mentioned above, the KFTC focuses on the following three areas of scrutiny to assess the anticompetitiveness of an agreement or practice: monopolies, monopolisation and abuse of monopolistic power in general; unfair collaborative activities; and unfair trade practices.

18 To what extent are technology licensing agreements considered anticompetitive?

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

In January 2012, the KFTC promulgated the Guidelines for Fair Patent Licensing Agreements. The KFTC states that the Guidelines for Fair Patent Licensing Agreements aim to prevent unfair practices in relation to patent licensing agreements (but can also apply to the licensing of other types of intellectual property rights) and to provide a reference point for understanding what may be viewed as fair licensing practices through recommended clauses, examples and explanations.

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

Although numerous instances of co-promotion and co-marketing arrangements exist among pharmaceutical companies, the KFTC has not specifically examined the legality of such practices in Korea to date. However, the KFTC published the results of a study that it commissioned on the potential for co-promotion and co-marketing agreements to have anticompetitive effects. According to this study, the potential for violation of the FTL exists to the extent the agreements include territorial or customer allocation, exclusive dealing, imposing minimum sales targets and resale price maintenance. The KFTC will likely review such arrangements with heightened scrutiny as shown by the fact that the KFTC's IPR investigation survey included specific questions regarding co-promotion and co-marketing arrangements with other companies.

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

See questions 18 to 19. While confidentiality provisions may reduce the likelihood of the agreements coming to the attention of the KFTC, they will not resolve the underlying issue of whether there is collusive activity.

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

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

A new statute, the Fair Agency Transactions Act (FATA), became effective on 23 December 2016. It expands provisions in the FTL that prohibit a type of unfair trade practice called abuse of superior bargaining position, which broadly govern the supplier-dealer or distributor relationship. The FATA also requires that a distributor agreement be entered into in writing. The FATA is designed to protect distributors who are recognised as socially and economically vulnerable. Enforcement of the FATA may result in an increase of complaints over unfair trade practices, increase in KFTC investigations, and increase in disputes concerning the termination of a distributor agreement.

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

As mentioned in question 8, the KFTC has already investigated and determined that a patent dispute settlement agreement violated the FTL through market allocation and interference with the business activities of another enterprise. Accordingly, we believe there is a high risk that a settlement of a patent dispute will expose the parties to potential liability for an antitrust violation. In addition, pursuant to an amendment to PAL in March 2015 linking the drug patent system and the drug registration and approval system, agreements between a patent holder and generic maker on the sale and distribution of the relevant product under dispute must be reported to the MFDS as well as the KFTC, exposing the settlement of a patent dispute to the risk of increased scrutiny by the KFTC for possible FTL violations.

The newly established Knowledge Industry Anti-Monopoly Division (see 'Update and trends') has announced that scrutinising pay-for-delay arrangements will be an area of focus.

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

Korea's pharmaceutical regulatory law did not impose obligations involving disclosure of HCP relationships or clinical trials until recently. However, the PAL was amended, as of December 2016, to require pharmaceutical suppliers to prepare reports on all financial transactions with HCPs and medical institutions within three months of the end of the fiscal year. This provision will be effective as of 3 June 2017. The Ministry of Health and Welfare may request that the companies submit such reports for the MOHW's review, and the pharmaceutical supplier must comply with this request absent justifiable circumstances for refusing. The reports are not required to be publicly disclosed, however, although it is possible that the data may become publicly disclosed in certain circumstances; for example, if the National Assembly requests the MOHW to submit the above data.

In addition to this, pharmaceutical companies are currently required to report their donations, sponsorship of academic conferences and HCP's participation therein, market surveys, exhibition and advertising to the KRPIA. However, this information is not publicly disclosed.

Anticompetitive unilateral conduct

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

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

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

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

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

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

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

See question 28.

The KFTC has in recent years identified potential abuse of IP rights as a priority issue for enforcement, particularly in the pharmaceutical (and IT) industries, and removed a key obstacle to enforcement – the lack of clear standards on what constitutes abuse of IP rights – by amending regulations, effective April 2010, (Guidelines on the Exercise of Intellectual Property Rights) (the Guidelines) that provide guidance on the scope of transactions to be covered and the standards for determining when the exercise of IP rights may constitute a violation of fair-trade law. The Guidelines provide that enforcement of IP rights is highly likely to be found unfair if the patent holder takes legal action to enforce a patent right despite being aware that the patent is not being infringed; or if it is 'objectively clear based on social norms' that infringement has not occurred. Further, if parties enter into a settlement agreement that is likely to cause undue delay to one of the parties in entering a market, and thereby impair competition in that market, such agreement is likely to be viewed as an anticompetitive exercise of IP rights.

As mentioned in question 18, the KFTC also promulgated the Guidelines for Fair Patent Licensing Agreements in January 2012. The KFTC identified potential issues with patent licensing agreements that include, but are not limited to, licence terms that restrict the licensee's ability to license or use competing technology and products because of confidentiality concerns, adequate allocation of benefits derived from improving the licensed patent technology and territorial restrictions.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

This is uncertain as we are not aware of any KFTC decision or court precedent on the issue. However, mounting criticism by consumer protection groups and regulators in Korea over 'evergreening' of patents and efforts by patent holders to protect their patent position could lead to increased scrutiny by the KFTC. Pressure in Korea for drug patent holders to protect their patent protections is high; the absence in Korea until recently of a link between the drug patent system and the drug registration and approval system (PAL amendments codifying the approval–patent linkage system entered into effect as of March 2012 (providing grounds for patent listing and notice to patent holders by generic makers utilising the safety and efficacy data of the original drug) and March 2015 (providing grounds for a patent holder to request delay of generic sales to MFDS for nine months and granting of marketing exclusivity to generic makers)) has meant that generic makers can and have applied for product approval sometimes far in advance of the original's patent expiration to secure a favourable pricing position and generic exclusivity. At the same time, the first entry of a generic into the Korean market will result in a substantial cut in the reimbursement price of the patent-protected original drug. Accordingly, defending the patent and the reimbursement price has become an important part of the life-cycle management of patented drugs.

Update and trends

Since the 'dual punishment laws' (under the Pharmaceutical Affairs Law and the Medical Services Law) came into effect (making it illegal for a pharmaceutical company to provide any kind of economic benefit to an HCP for the purpose of promoting the sale of its products and also illegal for an HCP to receive such benefit), the public prosecutors' office has taken the lead in enforcement against corruption in the industry.

However, (since its 2011 industry sweep) the competition authority continues to view the pharmaceutical industry as being at high risk of corruption and uses the prohibition against unfair customer solicitation under the FTL to root out improper financial relationships between the industry and HCPs.

The competition authority also continues to perceive the pharmaceutical industry as high risk in terms of unfair trade practices, in light of the fact that market power is concentrated in a relatively small number of large players transacting for the most part with smaller distributors and wholesalers. In this vein, the competition authority has taken a strict stance against perceived abuses of superior bargaining position on the part of these large players: for example, early termination of contracts, interference with business, performance targets, and minimum purchase requirements. The recent enactment of the FATA is in line with this general position.

In December 2016, the KFTC established a new Knowledge Industry Anti-Monopoly Division, in order to strengthen expertise in knowledge-based industries such as IT and pharmaceuticals/biotech. The new Division will investigate for abuse of dominant position and unfair trade practices in these industries and also advise on policy. Its establishment indicates the KFTC's desire to step up enforcement in these sectors, and it is possible that the Division may conduct industry-wide investigations in addition to inquiring into whistleblower reports. As discussed, the KFTC has announced that pay-for-delay arrangements will be among the Division's areas of focus.

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

There is no regulation that prohibits a patent holder from marketing or licensing its original drug as an authorised generic, or allowing a third party to do so. Unless there is a negative system under the applicable laws, it will be safe to say that marketing or licensing authorised generics is permitted under Korean law. In fact, there have been a number of cases of such arrangements in Korea with the purpose of gaining a head start on the competition in the relevant market.

An example is a co-marketing arrangement whereby a patent holder licenses a generics company to produce and sell a generic version of a brand-name product, in effect creating an authorised generic product that enjoys the same original drug reimbursement pricing. To date, the KFTC has not taken issue with the potential anticompetitive effects of this arrangement, but given the recent attention that the KFTC has paid to the issue of co-promotion and co-marketing including its IPR investigation generally, we cannot rule out the possibility that the KFTC may change its stance on this issue.

There are also downsides: authorised generics can lower the prices of the original drugs; and under the Patent Linkage System, an originator company may list its product-related patent, in which case a generic company will be required to notify the originator company of its generic approval application, if challenging the listed patent.

The originator company, thus notified, may request a temporary stay of sales of the generic. However, once an approval is made effective for a generic, the same in substance, dosage, usage and strength (ie, there is already an authorised generic in the market), the MFDS may dismiss such a request for a stay.

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

This issue is difficult to address, as there have been few KFTC findings of violation of antitrust law compared to other sectors in the pharmaceutical sector to date.

However, one of the few cases that does exist, involving resale price maintenance, suggests that the specific features of the pharmaceutical sector are not likely to go far in providing an objective justification for conduct that would otherwise be infringing antitrust rules. In that case, companies argued that they were forced to require distributors or wholesalers to sell their pharmaceutical products at a specific price, because of reimbursement rules that allow regulators to reduce reimbursement prices of drugs if the regulators find through surveys that wholesalers or distributors have supplied the drugs in question to hospitals, clinics or pharmacies at prices lower than the reimbursement prices for the drugs. The KFTC rejected these arguments.

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

Not applicable.

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The basic legislation and regulations specific to pharmaceutical products are set out in the following:

- the General Health Law;
- the Regulations on Health Inputs;
- the Regulations on Advertising;
- the Regulations on Clinical Research;
- the Federal Consumer Protection Law;
- diverse Mexican Official Standards; and
- the Pharmacopeia.

The above regulatory framework is enforced by:

- the Ministry of Health;
- the Federal Commission for the Protection against Sanitary Risks (COFEPRIS);
- the Ministry of Economy at the federal level; and
- the Federal Consumer Agency.

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

The General Health Law and the Regulations on Health Inputs are the main legal statutes setting forth provisions aimed at providing for adequate sanitary control of products, services and facilities relating to pharmaceutical products. These provisions include aspects such as those general principles for the access of products and services, the requirements and restrictions for the proper handling, distribution and retail of products depending on their category (eg, over-the-counter drugs (OTCs), prescription medicines, controlled substances) through the appropriate channels and also with respect to the requirements that need to be complied with by facilities involved in the marketing and distribution of pharmaceutical products.

Ancillary statutes such as the Regulations on Advertising, Mexican Official Standards and the Pharmacopeia set forth additional and specific requirements concerning the advertising and labelling of pharmaceutical products, good manufacturing practices and technical specifications concerning the activities and facilities involving the distribution of the products.

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

Self-regulated pricing control

As part of a government programme to modernise the pharmaceutical industry known as PROMIF, in 1996 the National Pharmaceutical Industry Chamber (Canifarma) and the Ministry of the Economy entered into a collaboration agreement for prices, which was amended in 2004. The agreement is mainly aimed at patented products, and sets forth a self-regulated pricing mechanism. This mechanism provides for private laboratories to determine a maximum price for sale to the public. Laboratories voluntarily adhere to this programme.

Retail price is registered with the Ministry of the Economy. This programme is based on the authority under the General Health Law for the Ministry of the Economy to set maximum prices on pharmaceutical products to the public.

Regulatory control of pharmaceuticals

The manufacturing, importation, exportation and marketing of pharmaceuticals in Mexico (either patented or generic) require a health registration issued by COFEPRIS. In the particular case of patented pharmaceuticals, the applicant must provide evidence that it is the title holder or licensee of the active ingredient's patent. Both the patent and the licence, as the case may be, need to be registered with the Mexican Industrial Property Institute.

In addition, the owner of a product's health registration is restrained from holding two registrations from pharmaceuticals that hold the same active ingredient, pharmaceutical form or formulation, unless those products are dedicated to the market of generic pharmaceuticals.

Competition legislation and regulation

4 Which legislation sets out competition law?

As a result of the recent amendments to article 28 of the Mexican Constitution (published 11 June 2013), the competition legislation has been completely overhauled. Two new autonomous constitutional enforcement agencies have been created:

- the Telecommunications Federal Institute, in charge of regulating, promoting and supervising the telecommunications, radio and TV industries, and acting as a competition enforcer in these sectors; and
- the Federal Economic Competition Commission (COFECE), the competition enforcement agency for any other sector or industry, including pharmaceuticals.

These new authorities took office on 10 September 2013, after the senate's ratification of most of the new commissioners.

As a result of the constitutional amendment, a new Federal Law of Economic Competition (the Competition Law) was enacted (in force as of 7 July 2014) along with its Regulatory Dispositions (in force as of November 2014).

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

Given the aforementioned constitutional amendment, COFECE, as a constitutionally autonomous body, is the only local agency in charge of enforcing the competition legislation and policy regarding the pharmaceutical sector. In addition, COFECE works closely with the authorities mentioned in question 1.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

Based on the statutory framework, COFECE can:

- impose significant fines, which will depend on several factors, such as the specific conduct, whether it is a second offence, intention to harm, duration of the practice, harm to the market;

- order up to a five-year disqualification sanction against pharmaceutical companies' executives, board members or employees, depending on the specific type of anticompetitive conduct;
- order the correction or suppression of a practice or concentration;
- impose conditions or behavioural or structural remedies in the event of concentrations, including divestments;
- order divestments in the case of second offenders; and
- use regulatory authorities in the event of barriers to competition or access to essential facilities or inputs.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Private parties may seek damages and lost profits through civil judicial actions (individual damage claims or class actions). However, private actions can only be initiated once a resolution is issued by COFECE declaring the commission of a conduct contrary to the law, and such a resolution becomes *res judicata*.

However, according to local statutory framework, only direct and immediate damages and lost profits may be awarded under Mexican law.

To our knowledge, thus far no damages have been awarded to competition civil plaintiffs, although in a case related to the pharmaceutical industry, the first damage action has been triggered by the Mexican Social Security Institute.

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

COFECE may conduct sector-wide inquiries. There have been recent inquiries into the financial and agro-industrial sectors. A similar inquiry into the pharmaceutical industry is expected, as it has been publicly announced by COFECE. These inquiries review the general aspects of the industry, including supply, manufacturing, distribution, government procurement and retail. In addition, COFECE has recently initiated an investigation in the off-patent pharmaceutical products segment, in order to publish a sector-study that aims to identify competition concerns and barriers.

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

The main non-governmental groups that participate in the pharmaceutical sector are Canifarma and the National Association of Pharmacies of Mexico. These organisations gather members of the industry to represent them in common issues arising within the sector, including antitrust concerns.

Review of mergers

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

COFECE analyses each merger considering the specific features of the industry involved. One of the most important issues that is considered when analysing mergers in the pharmaceutical industry is that of pipeline products. Normally, future products are not considered when reviewing other industries, however, they have been considered when reviewing mergers of pharmaceutical companies.

Investment in research and development in the pharmaceutical industry has also been subject to discussion by COFECE, which considers investment a significant barrier to entry for new participants.

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

The product market for human pharmaceuticals has been divided into three main sectors: active substances, future products, and pharmaceutical specialties.

Within the area of these main sectors, the markets are defined on the classification provided by the anatomical therapeutic classification level 3 (ATC3) used by the World Health Organization. Notwithstanding the foregoing, COFECE does not consider this classification to be a definitive product market definition, but a good starting point. The authority analyses whether the products included in each relevant ATC3 class are in fact substitutes, and if other products classified under different classes may compete with the products in question, considering, among other elements, whether they treat the same diseases, the different circumstances for their use and the prices of the products.

In addition, COFECE has found that OTC products and prescription products are not close substitutes, considering differences in regulation and prices (Case CNT-045-2014 – *Bayer/Merck*).

The geographic market has generally been defined as the Mexican territory.

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

The law allows for the parties to invoke efficiency gains to address antitrust concerns. However, depending only on efficiencies is a hard proposition, as the parties would need to prove, *ex ante*, that those efficiencies would actually benefit consumers.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

The first step of the analysis is based on the calculation of the HHI index. A combined market share exceeding the high 30s will normally exceed the HHI index and would be subject to thorough scrutiny. Other elements such as barriers to entry, efficiency gains and the presence and power of competitors are considered in the analysis.

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

The analysis with respect to pipeline products is made in relation to the products already marketed by the parties in the same ATC3 class. The analysis is similar to what is explained in question 11; mainly based on the market shares of the parties and the existence and presence of actual and potential competitors.

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

The typical remedy would be the licensing or transfer of specific products (CNT-017-2010 – *Novartis/Nestlé*). It is common for the Mexican regulator to review remedies imposed in other jurisdictions and review whether the effects of those remedies also address concerns in Mexico, without the need to impose a specific Mexico remedy. In addition, on a more recent case, COFECE conditioned its clearance to an obligation from the acquiring party not-to-buy certain specific products considering that such acquisition will increment the acquirer's market power as a result of its strong portfolio-product presence in certain specific markets (CNT-086-2016 – *Sanofi/Boehringer*).

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

The acquisition of a patent would be considered a concentration under the Competition Law, and would be subject to reporting requirements if any of the following thresholds is met:

- the transaction involves an act or series of acts, regardless of the place of execution, amounting to the equivalent of 18 million times the minimum general wage in force for the federal district or more;
- the transaction involves an act or series of acts with an accumulation of at least 35 per cent of the assets or capital stock of an economic agent, whose assets in Mexico or annual sales generated in Mexico involve more than the equivalent of 18 million times the minimum general wage in force for the federal district; or
- the transaction involves an act or series of acts with an accumulation in Mexico of assets or capital stock higher than 8.4 million times the minimum general wage in force for the federal district, and the transaction involves the participation of two or more economic agents with assets in Mexico or annual sales originated in Mexico, jointly or separately, of 48 million times the minimum general wage in force for the federal district.

Licensing of intellectual property rights may be deemed concentrations. Patent licensing involves the granting of the right for a licensee to use or exploit the patent for a specific period of time in a particular territory. Personal rights under Mexican law (such as a patent licence) are considered moveable goods (or assets, if defined from an economic standpoint). The authorities consider as a concentration, among others, the acquisition of control (without making reference to whether this control is temporary) of assets. Similarly, if one makes a strict interpretation of the definition of a concentration, a long-term supply agreement may be considered as one if, as a result thereof, one of the parties acquires control of the other. However, it would not be easy to make such an argument, and as far as we know, no filing has been made of a supply agreement as a concentration. This needs to be reviewed on a case-by-case basis.

Anticompetitive agreements

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

The Competition Law distinguishes between two types of monopolistic practices (including agreements), classifying them as absolute or relative. Absolute monopolistic practices are best known as horizontal practices or cartels, because they take place among direct competitors.

In a limitative and exhaustive manner, the Competition Law defines absolute monopolistic practices as those agreements (tacit or explicit), covenants, arrangements or combinations among competitors whose object or effect is to fix or manipulate prices, restrict output, segment markets, rig bids and exchange information with any of the foregoing objects or effects. As in many other jurisdictions, these practices are sanctioned under a *per se* rule so the enforcer only has to prove their existence in order to sanction them.

The Competition Law also prohibits relative monopolistic practices, which in general occur among economic agents in different levels of the distribution chain, such as between a manufacturer and a distributor. These practices are also best known as vertical restraints or abuse of dominance conducts.

The law acknowledges that these types of practices may have both competitive and anticompetitive effects, depending on their application. Therefore, the Competition Law provides for different criteria to analyse whether these practices should be considered monopolistic, and thus prohibited. In this regard, the following elements must be assessed and determined:

- the relevant market (both product and geography);
- whether the economic agents in question have substantial power (individually or jointly);
- whether there are any exclusionary effects; and
- efficiency gains resulting from the conduct that may have a favourable effect on the competition process.

Assuming that the economic agent or agents in question have individual or joint substantial power in the relevant market (or relevant markets), the authority must determine whether the particular conduct falls within any of the specific conducts provided in the Competition Law as relative monopolistic practices and whether efficiency gains could counter potential anticompetitive effects. These practices are listed in question 24.

18 To what extent are technology licensing agreements considered anticompetitive?

Technology licensing, as such, is not considered as an absolute or relative monopolistic practice. Anticompetitive concerns may be raised depending on the specifics of the agreements, the parties involved and the structure of the market. See questions 17 and 24.

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

Since these agreements normally involve promotion and marketing activities only, COFECE has raised no anticompetitive concerns, although it has reviewed references to these types of agreements under merger control cases.

Update and trends

The pharmaceutical industry has been under constant scrutiny by COFECE. COFECE has initiated several investigations that involve different segments and markets of the local pharmaceutical industry, including a recently-opened cartel investigation (May 2016) that might involve all players of the local industry, as it is opposed to the production, distribution and commercialisation of pharmaceutical products in Mexico.

Likewise, in February 2017, the Investigating Authority of COFECE brought criminal charges before the Federal General Attorney in order to prosecute individuals who were allegedly involved in collusive behavior over a public procurement procedure in the public health sector. This is the first time a competition authority in Mexico has requested that the General Attorney initiate a criminal investigation against potential offenders since cartel behaviour was introduced as a felony in Mexico back in 2011.

In addition, COFECE recently conditioned a deal between Sanofi and Boehringer Ingelheim involving the acquisition of Boehringer consumer healthcare business. COFECE conditioned the transaction subject to the obligation that Sanofi will not acquire certain medicines from Boehringer, as COFECE considered that the competitive pressure that Boehringer exercises over Sanofi would be lost and the combination would have resulted in a price increase to the detriment of consumers regarding the over-the-counter cough-phlegm medicines market.

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

See question 17. Also, exchanges of information between competitors shall be carefully reviewed on a case-by-case basis. Any exchange of information, whether directly or through third parties, that has the effects set forth in question 17, is prohibited and subject to significant fines and, potentially, criminal liability.

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

As further discussed in questions 17 and 24, for vertical agreements to cause concerns the economic agents in question shall have substantial power in the relevant market. Of these practices, the ones most likely to cause concern are related to exclusivities, price discrimination and loyalty rebates.

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

In Mexico, there have been no cases investigating patent settlements to delay the entry of generic products. However, these could be seen as market segmentation agreements between competitors. See question 17.

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

To avoid antitrust scrutiny, companies shall take every measure to avoid exchanges of sensitive information among competitors, including confidentiality agreements, providing only the information required to comply with the set goals and avoid direct contact with competitors as much as possible. There are no specific exemptions to the pharmaceutical industry on exchange of information among competitors. Likewise, COFECE has expressed certain concerns about discussions and contacts within commercial associations and chambers, so companies should always participate carefully in these types of gatherings.

Anticompetitive unilateral conduct

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

COFECE must determine if the conduct in question has, as purpose or effect, the wrongful displacement of other agents from the market, the

substantial prevention of their access or the establishment of exclusive advantages to the detriment of any third parties in the following cases:

- exclusivities, including imposition on a party not to manufacture or distribute goods or render services for a specific period of time;
- resale price maintenance;
- tying arrangements or sales;
- prohibition from using or selling products of third parties;
- a refusal to deal;
- boycotts;
- predatory pricing;
- discounts or incentives with the requirement not to use, acquire, sell, market or supply goods or services of third parties;
- cross-subsidies;
- discriminatory pricing;
- access to essential facilities; and
- any action by one or several agents to increase the cost or obstruct the productive process or reduce the demand faced by competitors.

See question 17 for a detailed analysis.

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

There is no set rule. COFECE must, in each case and for each market: analyse market shares; the structure of the market; whether competitors have the force to counter dominant conducts; barriers to entry; access to financing; and raw material, among other elements.

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

No. COFECE has not defined markets so narrowly. The authority must consider the existence of a substitute or potential substitutes.

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

Not applicable.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

The potential liability will depend on the specific strategy, the efficiencies that may be generated with respect to that strategy, and whether the patent holders are deemed to have substantial power in the market.

There is more flexibility during the introductory stages of a product. In fact, introducing a product into the market is considered an example of the efficiency gains recognised by the Competition Law.

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

They can do so for the term of the patent (which has a 20-year maximum).

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

There is no specific exemption on the application of antitrust law for the pharmaceutical industry.

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

Not applicable.

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The pharmaceutical market in Poland is regulated by a number of legal acts.

General provisions governing the whole pharmaceutical sector, manufacturing of pharmaceutical products, marketing, authorisation and supervision are included in the Pharmaceutical Law dated 6 September 2001 (the Pharma Law). The Pharma Law is subject to parliament's continuous amendments in order to adapt the provisions of pharmaceutical law to the changes observed in the market and in the scientific conditions, as well as in order to provide proper harmonisation with EU law. The Pharma Law has been amended several times since the date of its coming into force.

The rules for pricing of pharmaceutical products that are reimbursed by the Polish state are included in the Act on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices dated 12 May 2011 (the Reimbursement Act). The Reimbursement Act was enacted as a result of implementation of the Council Directive dated 21 December 1988, relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ No. L 40 of 11 February 1989, p 8). The Reimbursement Act introduces a price control system as it regulates, inter alia, the rules, procedure and criteria for setting official selling prices of medicines and also official wholesale margins and official retail margins. The Ministry of Health publishes a list of reimbursed medicines with their fixed prices that cannot be modified by market participants. Over-the-counter (OTC) medicines that are not included in the list published by the Ministry of Health can be freely priced by pharmaceutical entities.

The Reimbursement Act is a natural element of the Polish healthcare system that is regulated by the Act on Healthcare Services Financed from Public Funds dated 27 August 2004. The healthcare system is managed and supervised by the National Health Fund.

There is no specific legal act for generic drugs regulation in Poland.

The Ministry of Health, The Chief Pharmaceutical Inspector and the State Pharmaceutical Inspection and its regional branches are entrusted with enforcing the rules of marketing, authorisation and pricing of pharmaceutical products. Body property depends on the nature of the case. Furthermore, the Office of Competition and Consumer Protection (the Competition Office) applies antitrust rules to the pharmaceutical sector.

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

The distribution of pharmaceutical products is regulated in the Pharmaceutical Law dated 6 September 2001. It includes the rules for wholesale distributors, retail distributors and also for pharmacy networks. Due to the amendment to the Pharma Law from February 2015, new provisions on manufacture, import and distribution of an active substance were introduced, as well as the definition of 'good distribution practice' deriving from the Directive 2001/83/EC of the European Parliament and of the Council dated 6 November 2001 on the community code relating to medicinal products for human use. There is also the Regulation of the Minister of Health dated 13 March 2015 on the requirements for good distribution practice (Journal of Laws 2015, item 381).

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

The Pharma Law contains the rules and requirements for advertising medicinal products and specifies the legal consequences of their violation. The issues connected with competition law are regulated exclusively in the Act on Competition and Consumer Protection dated 16 February 2007 (the Competition Act).

Moreover, certain anticompetitive practices, such as, for example, the barriers to entry into the market, are also regulated in the Act on Combating Unfair Competition dated 16 April 1993.

Competition legislation and regulation

4 Which legislation sets out competition law?

The Polish Competition Law consists of:

- the Act on Competition and Consumer Protection dated 16 February 2007 (Journal of Laws 2015, item 184), mentioned above as 'the Competition Act';
- the Regulation of the Council of Ministers dated 17 April 2015 on the exemption of certain types of technology transfer agreements from the prohibition of competition-restricting agreements (Journal of Laws 2015, item 585);
- the Regulation of the Council of Ministers dated 23 December 2015 on the method of calculation of turnover of undertakings participating in concentration (Journal of Laws 2015, item 79);
- the Regulation of the Council of Ministers dated 23 December 2014 on the notification of the intended concentration of undertakings (Journal of Laws 2015, item 80); and
- the Regulation of the Council of Ministers dated 23 December 2014 on the manner and procedure with respect to an application for renouncement of imposing a fine or its reduction (Journal of Laws 2015, item 81).

As an EU member state, Poland abides by the relevant EU laws concerning competition, as well as recognising the established practice of the appropriate EU authorities and the jurisprudence of the European Court of Justice (ECJ) in that matter.

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

The relevant authorities are the president of the Competition Office and the relevant Voivodship Pharmaceutical Inspectors.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

The president of the Competition Office is entitled to issue a decision recognising the practice as restricting competition and order the practice infringing the relevant prohibitions to be discontinued. Such

a decision can be issued in case of the abuse of a dominant position on the relevant market by one or more undertakings, or an infringement of the prohibition of competition-restricting agreements that have as their object or effect the elimination, restriction or any other infringement of competition on the relevant market.

Whenever the intention of concentration has not been notified to the president of the Competition Office (and in other similar cases) and the concentration has been implemented and restoration of competition in the market is otherwise impossible, the president may, by way of a decision, and specifying a time limit for its implementation under conditions specified in the decision, order in particular:

- division of the merged undertaking under conditions defined in the decision;
- disposal of the entirety or a portion of the undertaking's assets;
- disposal of stocks or shares ensuring control over the undertaking or undertakings; or
- dissolution of the company over which the undertakings have joint control.

If the decision addressee does not comply with the above-mentioned decision in the prescribed term, the president may, by way of a decision, accomplish the division of the undertaking. The president shall act as the statutory bodies of the companies participating in the division. Moreover, the president may apply to the court for the annulment of the agreement, or for undertaking other legal means in order to restore the previous status.

The president of the Competition Office is entitled to impose, by way of a decision, a maximum fine of 10 per cent of the turnover generated in the financial year preceding the year in which the fine is imposed, if the undertaking has, even unintentionally, infringed certain anticompetitive laws.

In previous years, the pharmaceutical giant Johnson & Johnson Poland has been fined twice by the president of the Competition Office for fixing the conditions of a tender with another entity in order to sell its medicine used for the treatment of anaemia.

In 2011, the pharmaceutical company Aflofarm Fabryka Leków sp z.o.o. was fined by the president of the Competition Office for misleading the patients by means of a television advertisement because the person appearing in the advertisement as a professor, who recommended the company's product, was not qualified to use that title.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

In Poland, the enforcement of antitrust rules is predominantly public. There is, however, a growing expectation that private enforcement of the antitrust rules will gain significance as a result of the Supreme Court judgment dated 2 March 2006. This judgment, following other judicature of the Supreme Court, authorised civil courts to conduct civil proceedings without the need to suspend them until the president of the Competition Office issues its decision regarding the anticompetitive conduct that gave rise to the proceedings. A plaintiff claiming damages is under obligation to actively prove in the court of law that the undertaking has infringed the competition, the loss that was caused by the anticompetitive behaviour and the causal link between the two.

Moreover, in case of class action lawsuits, the Act on Class Action Lawsuits Proceedings dated 17 December 2009 shall be applicable. This act regulates civil law proceedings connected with claiming damages of one kind, based on the same factual basis and claimed by at least 10 jointly acting plaintiffs. This procedure can be used for the purpose of protecting consumers, for example for damage caused by dangerous products or as a consequence of tort.

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

The president of the Competition Office may, acting ex officio and by way of a resolution, institute preliminary proceedings, if the circumstances indicate that the provisions of the competition law might have been infringed regarding a given branch of the economy, or regarding protection of consumer interests and in any other cases provided for by the Competition Act. The preliminary proceedings may lead to investigation of the relevant market sector, including determination of the structure and degree of concentration implemented.

In 2006, the Competition Office investigated the pharmaceutical sector and focused on the medicines wholesale market. In 2009, it initiated preliminary proceedings in order to explore whether manufacturers of pharmaceuticals comply with antitrust laws. For that purpose, the Competition Office conducted a questionnaire investigation and analysed the agreements concluded between major producers and distributors with wholesalers. The collected data revealed the possible occurrence of the competition-restricting practices in the drug market (such as introducing certain limitations and rejecting orders from wholesalers that exceed them), used to limit the export of drugs from Poland to other member states.

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

NGOs, trade associations or consumer groups are not authorised to initiate any anticompetitive proceedings. The entrepreneurs often, however, unofficially notify the Competition Office about potential competition law infringements. For example, more than 100 Polish hospitals claimed that the National Health Fund has been abusing its dominant position on the relevant market by imposing onerous agreement terms and conditions on the hospitals and consequently yielding unjustified profits. As a result of the intervention, the president of the Competition Office instituted preliminary proceedings.

The Polish Administrative Code dated 6 June 1960, which applies to proceedings conducted before the president of the Competition Office, provides for the possibility of initiating proceedings due to public interest interventions. The legal position of the intervening parties, such as social organisations, is very similar to the position of a party.

Review of mergers

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

There are no specific rules applicable to mergers in the pharmaceutical industry in Polish competition law, therefore general rules of the Commercial Companies Code shall apply. Pursuant to the Competition Act, the participants of a planned transaction are obligated to obtain prior consent from the president of the Competition Office. The law provides also for the possibility of exemption from the obligation to notify the president, if the potential impact of the planned transaction to the relevant market is insignificant.

The consent to mergers may be conditional. The president of the Competition Office may impose certain conditions in order to ensure that the competition in the market will not be significantly reduced. These conditions may be of a structural nature and include, for example, an obligation to dispose of certain assets.

A recent example of a major merger in the Polish pharmaceutical industry was *Polfa Warszawa SA/Polpharma SA* (Decision of the President of the Competition Office DKK – 23/2012). In this case, the president of the Competition Office examined the entry barriers to the relevant market for new entrants. According to the president, the effects of the merger may have led to a significant increase of the prices of certain medicines. The merger received the relevant consent, however, the president ordered that Polpharma SA dispose of the entirety of its rights to three medicines together with the disposal of the benefit earned from the business that was not connected with the investor's group of companies involved in the merger.

Furthermore, the president of the Competition Office has recently given consent for three acquisitions in Poland's pharmacy sector. In the first, BRL Center Polska sp z.o.o., which operates pharmacies under the Dr Max brand, acquired pharmacies belonging to the company Medea Holding sp z.o.o., a chain of stores spread across separate geographic markets to such an extent that the Authority anticipated no threat to competition on any of the local markets (Decision of the President of the Competition Office DKK – 13/2016).

In another application, the company Cefarm – Warszawa SA asked for permission to acquire the company Gama Farmacia. Cefarm – a retailer of pharmaceutical products and provider of logistics, is also a subsidiary of Farmacol, which, in addition to performing retail operations, is also a wholesaler of pharmaceutical products. The

Competition Office's proceeding in the case revealed that the transaction shall not reduce competition: while both companies run general pharmacies, they are located in separate geographic markets. In addition, Farmacol's share in the pharmaceutical product delivery market in voivodeships where the pharmacies planned to be taken over were located, has not exceeded 30 per cent (Decision of the President of the Competition Office DKK – 12/2016).

In addition, Polish law contains some specific requirements connected with setting up a new pharmacy, another consequence of a merger. Pharmaceutical law in Poland does not permit a company to set up a new pharmacy if the company itself, the entities that it controls or members of the capital group that controls it, run more than 1 per cent of pharmacies in a given voivodeship. The antitrust law, on the other hand, assumes that if the company has a 40 per cent market share, it has a dominant position. The president of the Competition Office shall agree to the concentration if the competition will not be restricted on a given local market and consumers will not lose their ability to choose a pharmacy.

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

In order to define the relevant market in the pharmaceutical sector, we need to follow the European Commission's standpoints. According to its decisions, the classification of medicinal products – the anatomical therapeutic chemical (ATC) classification system adopted by the European Pharmaceutical Market Research Association, shall be applied. This classification allocates drugs into 16 groups divided by their therapeutic properties and each group is also divided into levels of drugs with similar chemical properties. Level three includes drugs that can be used as substitutes in treating the same illnesses because of their therapeutic properties. Precisely for this reason, the Commission in its decisions assumes that products pertaining to level three or four within the same ATC category shall constitute a relevant product market. Moreover, products belonging to the same classification category and level may sometimes constitute separate relevant product markets due to the distinction between prescription medicines and OTC medicines. Prescription products and OTC products belong to different relevant markets despite their identical therapeutic properties, when the group of potential consumers is different and when they entail different risks, payment or reimbursement rules. Additionally, the Commission explained that the relevant market may be identified not only for drugs that are already available, but also for products that are still to be placed on the market.

The relevant geographic market of drugs should be considered only at a national level. The general assumption is that the relevant geographic market of drugs comprises the markets of individual member states, as each country has its own specific legal regulations regarding placing products on the market, distribution, manufacturing and packaging or different reimbursement schemes. For that reason there are different conditions for competition in each market.

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

The Office of Competition and Consumer Protection shall inspect and investigate each case individually, especially within the competence of control. Therefore each case is examined individually and in certain cases antitrust concerns might be based on such arguments. The Court of First Instance argued in its judgment in the case T-168/01122 (*GlaxoSmithKline Services Unlimited*), that the conduct of companies in the relevant market should be examined in the legal and economic context of their operation, considering the specificity, which in the pharmaceutical sector is decided by the mechanism of complete or partial reimbursement of medicines under the social insurance system. The coexistence of different national regulations relating to the fixing of prices of pharmaceuticals and principles of their reimbursement may distort competition and lead to the strengthening of a specific partitioning of national markets. However, it does not mean there is no competition among companies in the sector. On the contrary, we observe a significant rivalry among manufacturers of medicinal products, which is mainly concerned with parameters other than price.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

A product and geographical overlap between merging parties may be considered problematic if it impedes effective competition in a relevant market, in particular if the merger causes the creation of a dominant position for any particular undertaking or in strengthening the dominant position the undertaking already possesses. Under the provisions of the Competition Act, it is legally presumed that an undertaking holds a dominant position in the market if its market share in the relevant market exceeds 40 per cent. In addition, two or more undertakings may have the joint dominant position in the relevant market.

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

Full analysis in the light of competition rules always requires the analysis of future products to be placed on the market. The European Commission has defined these products that are in the pipeline as products not yet present on the market, but at an advanced stage of development, normally at the latest stage of clinical testing. In light of the above, the ability to define the relevant product market depends not only on the stage of research and development of projects but also on the assessment of potential competition. These potential competition assessments involve identifying the competitors of the undertaking concerned that are able to affect the undertaking's behaviour and prevent it from behaving independently of competitive pressure. The president of the Competition Office assesses the relevant market.

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

The president of the Competition Office has great scope of discretionary power to apply different remedies provided by law. The president may issue a decision imposing a maximum fine of 10 per cent of the turnover achieved in the financial year preceding the year in which the fine has been imposed, if an undertaking, even unintentionally, performs a merger or acquisition without the president's prior consent. Furthermore, structural sanctions may be applied if the merger is proved to be anticompetitive. The president shall, by way of a decision, prohibit the implementation of a concentration if it results in a significant impediment to competition in the market, in particular by the creation or strengthening of a dominant position in the market. Furthermore, the president shall issue a consent to implement a concentration when, upon fulfilment of the conditions by undertakings intending to implement a concentration, competition in the market will not be significantly impeded, in particular by the creation or strengthening of a dominant position.

The president may impose upon an undertaking or undertakings intending to concentrate an obligation, or accept commitment on their part, in particular:

- to dispose of the entirety or part of the assets of one or more undertakings;
- to divest control over a specified undertaking or undertakings, in particular by disposing of a specified block of stocks or shares;
- to dismiss one or more undertakings from a position on the management or supervisory board; or
- to grant a competitor an exclusive licence.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

Generally, the acquisition of IP rights does not fulfil the merger definition under the Competition Act. However, according to article 13 of the Competition Act, the intent to concentrate is subject to notification submitted to the president of the Competition Office. The obligation concerns the intention to acquire a portion of another undertaking's assets (the entirety or part of a business enterprise) by an undertaking, if the turnover achieved by the way of such assets in either of the two financial years preceding the notification exceeded the equivalent of €10 million.

In view of the above, such an acquisition of patents or licences may be subject to merger reporting and approval, provided that the

statutory turnover limits are exceeded and provided that the specific IP rights constitute a part of a business enterprise of the undertaking to which the turnover achieved through the sale of products in the relevant market can be unambiguously assigned, even though it does not form an independent organisational unit of the enterprise.

Anticompetitive agreements

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

Article 6 paragraph 1 of the Competition Act includes a catalogue of competition-restricting agreements that have as their object or effect elimination, restriction or any other infringement of competition in the relevant market. The following, in particular, shall be prohibited:

- fixing directly or indirectly prices and other trading conditions;
- limiting or controlling production or sale as well as technical development or investments;
- dividing sale or purchase markets;
- applying onerous and inconsistent contractual terms and conditions to equivalent agreements with third parties, thus creating diversified conditions of competition for those parties;
- making conclusion of an agreement subject to acceptance or fulfilment by the other party of some other performance that is not linked in material or customary terms with the subject matter of the agreement;
- limiting access to the market or eliminating from the market undertakings that are not parties to the agreement; and
- collusion between undertakings entering a tender, or by those undertakings and the undertaking being the tender organiser , of the terms and conditions of bids to be proposed, particularly as regards the scope of works or the price.

The above-mentioned prohibitions regulated in article 6 paragraph 1 of the Competition Act shall not apply to agreements concluded between competitors, provided that their combined share in the relevant market covered by the agreement does not exceed 5 per cent, and between the non-competing undertakings, provided that none of them has a share exceeding 10 per cent in the relevant market covered by the agreement.

The Polish competition law also established an exception, similar to the one regulated in article 101(3) of the Treaty on the Functioning of the European Union (TFEU). Therefore, according to article 8 of the Competition Act, the prohibitions referred to in article 6 paragraph 1 shall not apply to agreements that at the same time:

- contribute to improvement of the production, distribution of goods or to technical or economic progress;
- allow the buyer or user a fair share of benefits resulting thereof;
- do not impose upon the undertakings concerned impediments that are not indispensable to the attainment of these objectives; and
- do not afford these undertakings the possibility to eliminate competition in the relevant market in respect of a substantial portion of the goods in question.

The Council of Ministers may, by way of a regulation, make exempt from the prohibition certain types of agreements that bring competitive benefits. The Council of Ministers has issued nine regulations in this area so far: four of them are in force.

Finally, the Competition Act prohibits abuse of a dominant position in the relevant market that may consist of, for example:

- direct or indirect imposition of unfair prices, including excessive or predatory pricing;
- long-time payment terms or other trading conditions;
- limiting production, sale or technological progress to the detriment of contracting parties or consumers;
- applying onerous or inconsistent contractual terms and conditions to equivalent agreements with third parties, thus creating diversified conditions of competition for those parties;
- making conclusion of an agreement subject to acceptance or fulfilment by the other party of supplementary obligations that are not linked in material or customary terms with the subject matter of the agreement;
- counteracting formation of conditions necessary for the emergence or development of competition;
- imposing onerous contractual terms and conditions, yielding to the undertaking's unjustified benefits; or
- dividing the market according to territorial, product, or entity-related criteria.

18 To what extent are technology licensing agreements considered anticompetitive?

Technology licensing agreements are covered by the European Union block exemption regulation No. 316/2014, on the application of article 101(3) TFEU to certain categories of technology transfer agreements, provided that market shares of the parties to such an agreement do not exceed stipulated thresholds and that the agreement does not include hardcore restrictions. This regulation is directly applicable in Poland. However, if the trade between the EU member states has not been affected, national antitrust law shall be applicable.

According to the Regulation of the Council of Ministers dated 17 April 2015 on the exemption of certain types of technology transfer agreements from the prohibition of competition-restricting agreements, anticompetitive behaviour is allowed if it does not contain hardcore restrictions of competition such as the limitation of output, price fixing, the market or customers allocation, or other restrictions that are excluded from an exemption. Moreover, the combined market share of the parties to the agreement shall not exceed 20 per cent when they are competitors and 30 per cent when they are non-competitors for any of them in the year preceding the conclusion of the agreement.

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

Polish legislation does not contain any specific provisions of law concerning co-promotion and co-marketing agreements. Therefore, the Competition Office shall follow EU law and practice.

In its Pharmaceutical Sector Inquiry Final Report dated 8 July 2009 (the Final Report), the European Commission defined co-promotion and co-marketing agreements as follows:

- co-promotion agreements: (joint) commercialisation of a specific medicinal product by both parties under one single trademark; and
- co-marketing agreements: commercialisation of a specific medicinal product by both parties under different trademarks.

At first glance, such definitions may seem clear. However, the assessment of these contracts under competition law can often be problematic as the relationships they create between the parties may fall under the scope of various regulations and guidelines. Such agreements may often lead to price fixing, the limitation of output, market allocation and similar.

The co-promotion and co-marketing agreements are usually part of a wider research and development agreements that are covered by the EU Block Exemption Regulation No. 1217/2010, on the application of article 101(3) TFEU to categories of research and development agreements. The agreement covered by the Block Exemption Regulation may be beneficial for its parties if their market share does not exceed stipulated limits and the agreement does not include hardcore restrictions.

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

Under article 6 of the Competition Act, the agreements between competitors including, for example, price fixing, limitations of output, market allocation or bidding cooperation will be considered anticompetitive. Moreover, the statistical cooperation or other exchange of information between the competing undertakings may be prohibited depending on the nature, age and frequency of the exchanged information, as well as the structure and transparency of the markets. Other horizontal agreements, such as research and development or specialisation agreements, must be assessed on a case-by-case basis, taking into consideration their effect on the market. In light of the above, it should be noted that there is no closed catalogue of prohibited agreements, which means that any other agreement concluded between competitors may raise competition concerns if the intention of such agreements may lead to the restriction of competition.

All these agreements often contain confidentiality clauses protecting the content of the agreement against disclosure. Such provisions have no effect on the operation of competition law and are thus ineffective.

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

Vertical agreements that include clauses restricting the buyer's freedom to fix resale prices and allocate territories or customers raise antitrust concerns. Another important clause that may raise antitrust concern in vertical agreements has been widely discussed in the *GlaxoSmithKline & Aseprofar* case, in which the ECJ stated that an agreement between a producer and a distributor of medicinal products, aiming to restore national barriers to trade between member states by differentiating products' prices to discourage parallel imports, restricts competition.

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

There is no Polish case law concerning the settlement of a patent dispute in the pharmaceutical sector in relation to an antitrust violation. However, as the Final Report shows, the agreements in which a manufacturer of generic pharmaceuticals agrees to keep its product off the market and intentionally delays its entrance against remuneration received from the manufacturer of an original pharmaceutical, are most probably of an anticompetitive character. Consequently, these activities lead to the restriction of competition, as well as to impeding innovation. The patent settlement agreements do not differ from other agreements and, therefore, must be assessed in the light of competition rules in the same way as any other agreements.

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

Such increased activity in pharmaceutical sector hasn't been observed.

Anticompetitive unilateral conduct

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

An undertaking is considered to be dominant if its economic strength allows it to behave independently of other competitors and customers in the market. The dominant position itself is not illegal under the competition law. According to article 9 of the Competition Act, the abuse of a dominant position in the relevant market is prohibited. Such an abuse of dominant position may take a wide range of forms. The Competition Act provides a list, including exemplary conduct such as:

- directly or indirectly imposing unfair prices, including excessive or predatory pricing, delayed payment terms or other trading conditions;
- limiting production, sale or technological progress to the detriment of contracting partners or consumers;
- applying onerous or inconsistent contractual terms and conditions to equivalent agreements with third parties, thus creating diversified conditions of competition for these parties;
- making conclusion of an agreement subject to acceptance or fulfilment by the other party of supplementary obligations that are not linked in material or customary terms with the subject matter of the agreement;
- counteracting formation of conditions necessary for the emergence or development of competition;
- imposing onerous contractual terms and conditions, yielding to the undertaking's unjustified benefits; and
- dividing the market according to territorial, product or entity-related criteria.

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

Under the Competition Act, an undertaking is considered dominant when its market position allows it to prevent effective competition in a relevant market, thus enabling it to act to a significant degree independently of its competitors, contracting parties and consumers. It is assumed that an undertaking holds a dominant position if its market share in the relevant market exceeds 40 per cent.

A jointly dominant position occurs when two or more undertakings are assumed to be dominant, namely, that their market share in the relevant market exceeds 40 per cent, and there exists a specific, mutual link of a structural, contractual or even informal character between the jointly dominant undertakings.

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

Holding a patent does not necessarily mean the patent holder has a dominant position. The dominance occurs if the holder possesses a high market share on the relevant market as a result of having the patent rights.

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

Generally, the application for the grant of a patent does not expose the patent owner to liability for antitrust violation, although such an application may lead to the creation or strengthening of the applicant's dominant position in the relevant market. According to the landmark *AstraZeneca* case decided by the ECJ in 2010, the Court indicated that AstraZeneca abused its dominant position in the relevant market by providing false information to patent authorities of different countries,

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leading to receiving the grant of the additional patent protection certificate. Additionally, the Court also found another of AstraZeneca's behaviours abusive, namely that selective deregistrations of marketing authorisation by AstraZeneca in some countries deprived the generics' manufacturers of the possibility of entering the relevant market with cheaper generics. Therefore, the abuse of legal procedures supporting IP rights protection constitutes a new anticompetitive form of abuse of the dominant position of a patent holder.

As mentioned above, the possession of a patent does not necessarily mean that the patent holder is a dominant undertaking. Moreover, having a dominant position does not constitute an antitrust violation itself. However, some of the dominant undertaking's conduct could be perceived as anticompetitive, for example, in situations when the purpose of this conduct is to prevent other companies from entering the market or to exclude potential competitors and restrict competition.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

It is rather unlikely that life-cycle management strategies undertaken by a patent owner could abuse its dominant position. The deciding factor here is whether those strategies aim to develop or protect goods or distort the competition.

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

There have been no issues regarding generics raised in Poland under the competition law so far.

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

The Polish healthcare system is financed from the public budget. The Minister of Health, acting on the basis of the Reimbursement Act, decides on a list of medicines that are refunded fully or partly. Thus, the state influences prices of pharmaceuticals published on the list by the Minister of Health. Therefore, general antitrust legislation regarding price fixing does not apply.

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

There has been no observed increase of national enforcement activity in relation to life-cycle management and settlement agreements with generics.

Portugal

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The main rules that set out such regulatory framework, mainly for marketing and authorisation of pharmaceutical products, are contained in the Medicines Act approved by Decree-law 176/2006 of 30 August 2006, as republished by Decree-law 128/2013 and further amended by Law 51/2014, of 25 August 2014.

Decree-law 97/2015 of 1 July 2015 created the National System for Health Technologies Assessment, which establishes rules concerning matters such as pricing and reimbursement. Such rules are complemented by the Ministerial Orders (Portaria) 195-A/2015, 195-B/2015, 195-C/2015 and 195-D/2015, all of 30 June 2015. There also separate orders that regulate the reimbursement of medicines for specific diseases (such as Order 330/2016 for MS) and medical devices (such as Order 35/2016 for test strips).

The reference countries used to determine the price of medicines in Portugal for 2017 that are referred to in these rules, are those determined by the Order (Despacho) 290-B/2016 of 10 November 2016.

The National Authority of Medicines and Health Products' (Infarmed) Regulation, approved by its Resolution 873/2013 of 6 March 2013, regulates the authorisation, manufacture, distribution and sale of allergen drugs destined for specific patients.

Decree-law 102/2007, of 2 April 2007, not only establishes the good clinical practices rules, but also the specific conditions applicable to the manufacturing or importing of such products.

Infarmed is the entity that regulates and is in charge of the supervision of matters related to pharmaceutical products and devices, and responsible for the enforcement of the applicable rules.

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

The Medicines Act contains all the legal rules pertaining to the distribution of pharmaceutical products.

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

The rules on parallel trade, authorisation and direct purchase of medicines, advertising and formation of prices are those that are most relevant.

Competition legislation and regulation

4 Which legislation sets out competition law?

Apart from EU legislation, which is also applicable in Portugal, the national legislation that sets out competition law is Law 19/2012 of 8 May (the Competition Legal Regime).

The Leniency Programme is regulated by Regulation No. 1/2013 issued by the Portuguese Competition Authority (AdC).

Other relevant legislation that does not set out competition law but is also applicable is:

- Decree-law No. 433/82 of 27 October 1982 (that approves the general regime on administrative offences), applicable, on a subsidiary basis, to the administrative procedure on anticompetitive agreements, decisions and practices, and to the judicial review of sanctioning decisions; and
- the Code of Administrative Procedure, since the general principles for administrative action are also applicable to sanctioning procedures under the Competition Legal Regime.

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

Although Infarmed is the entity that regulates the pharmaceutical sector, the competent authority to investigate and decide on pharmaceutical mergers as well as the anticompetitive effect of conduct or agreements in the pharmaceutical sector is the AdC. It is the AdC's mission to ensure the enforcement of competition rules in Portugal. Therefore, if Infarmed is aware of a potential breach of competition rules, it must forward the matter to the AdC for analysis and further follow-up. The AdC should ask the opinion of Infarmed before taking any action.

Decisions of the AdC are subject to appeal to the Competition, Regulation and Supervision Court.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

The AdC may impose any structural or behavioural measures it deems necessary to cease the restriction of competition or its effects on pharmaceutical companies involved in anticompetitive practices. Structural measures can only be imposed when there is no behavioural measure that would be equally effective or, should it exist, would be more onerous for the party concerned than the structural measures themselves.

For example, the AdC may declare void certain rules or clauses included in the agreements that are deemed to be anticompetitive, or even declare that the agreement as a whole is contrary to competition rules and declare the cessation of its effects.

During an eventual investigation, if the AdC believes that the practice under investigation may cause serious and irreparable or hardly reparable damages then, after requesting the opinion of Infarmed, it may order the suspension of such practice or any other measures that could reinstate competition or that are indispensable for the final decision to have a useful effect.

Whenever the AdC concludes that there are circumstances or behaviour that affect competition in the markets or economic sectors analysed, such as the pharmaceutical sector, and after it has identified the circumstances in the market or the behaviour of undertakings or associations of undertakings that affect competition, and to what extent, it must decide on which behavioural or structural measures it considers appropriate to prevent, remove or offset the effects. The relevant report is then sent to Infarmed. Furthermore, the AdC may recommend the application of behavioural or structural measures considered appropriate to restore or ensure competition in the market. Depending on the case, the recommendations may be submitted to the government and Infarmed or to the government and other entities (where what affects competition does not arise from pharmaceutical laws and regulations).

In case of breach of competition laws, the AdC may also apply fines of up to 10 per cent of the turnover of the concerned party or, in the case of an association of undertakings, of the aggregate turnover of its members, and the following sanctions:

- publication in the Official Journal of the Portuguese Republic and in a national, regional or local newspaper with a large circulation, according to the relevant geographical market, at the expense of the party concerned, with an extract of the decision imposing a sanction; and
- a ban of up to two years on the right to take part in public tenders, in those cases where the practice that has led to an administrative offence punishable with a fine has occurred during or because of such procedures.

The AdC may also apply a periodic penalty payment when a decision applying a sanction or imposing the adoption of certain measures is not complied with. Such penalty may not be higher than 5 per cent of the average daily turnover in the year immediately before the decision, per day of late payment.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Private parties may report situations believed to be breaching competition rules to the AdC or Infarmed and require that certain remedies are applied.

However, to be indemnified from the damages arising from the anticompetitive conduct or agreements by pharmaceutical companies one can, preferably based on a decision of the AdC acknowledging the same, file the competent judicial lawsuit, although the court would not be bound by such decision and would freely evaluate the evidence produced. It is also possible to file a class action aimed at protecting consumers' interests that are harmed by the anticompetitive conduct or agreement. The class action can be used to prevent or cease the anticompetitive conduct or agreements.

Considering that a decision, particularly a judicial decision, may take a long time to be issued, a private party could file precautionary proceedings in order to obtain a protective order of its interests. Such protective order could, for example, be the suspension of the execution of the agreement or the prohibition to pursue certain conduct.

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

Yes, the AdC may conduct such inquiries. In fact, the performance of economic surveys represents a significant part of the AdC's activities since they are used to supervise and monitor the markets and they allow the AdC to verify any circumstances that may indicate distortion or restriction of competition.

When the AdC concludes that there are particular circumstances or behaviour that affect competition in the markets or economic sectors analysed, such as the pharmaceutical sector, it should inform the sector's regulatory authority, in this case Infarmed, of the issue immediately, so as to allow it to issue an opinion within the time limit stipulated by the AdC.

Otherwise, the AdC requests a non-binding opinion to Infarmed before it issues its conclusions regarding the market study and inquiries in the pharmaceutical sector.

The last market analysis the AdC made of the pharmaceutical sector was in 2007, called the 'Framework of the Pharmaceutical Activity', and was issued following the participation in a colloquium organised by the parliament's Health Commission, which it summarises. This document was preceded by another market study carried out in 2005, regarding the competitive situation in the pharmacies sector.

The Framework of the Pharmaceutical Activity study identifies five types of restrictions to competition arising from the legislation applicable to pharmacies: restrictions to entry into the market; reserved activities; structure-related restrictions; pricing restrictions; and advertising restrictions.

Most of the restrictions identified by the AdC were taken into consideration by the government and the AdC's recommendations are reflected in the new regime of pharmacies issued in 2011.

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

Trade associations and other private organisations (such as law firms) are consulted prior to the approval of new competition rules – this was the case prior to the approval in 2012 of the new Competition Legal Regime that replaced the former Competition Act.

Like other entities and individuals, NGOs, trade associations and consumer groups may report situations that they consider to be in breach of competition law. Such reports are then investigated by the AdC. The AdC is obliged to register all claims received.

As referred to above, it is also possible for such organisations to file class actions when aimed at defending consumers' interests.

The trade association that plays the major role in the application of competition rules to the pharmaceutical sector is the Pharmaceutical Industry Association known as Apifarma (which is itself a member of the International Federation of Pharmaceutical Manufacturers & Associations).

Apifarma was founded in 1975 and represents more than 120 companies in the pharmaceutical sector. It has its own code of ethics. Many of the issues affecting the pharmaceutical industry are discussed by state bodies with Apifarma instead of with the companies.

As for pharmacies, their trade association, the Pharmacies Association, is also an important player in this sector.

Review of mergers

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

So far, the AdC has hardly opposed any mergers between two pharmaceutical companies. Since the AdC has a significant track record on these matters, it is aware of the sector-specific features of such cases.

Generally speaking, the AdC has decided not to oppose the mergers of which it was notified because it considered that they did not create or reinforce a dominant position that would cause barriers to effective competition in the identified relevant markets.

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

The geographic market defined by the AdC, following the practice of the European Commission, is generally the national market, although there may be situations where the relevant geographical market could be one of the Portuguese autonomous regions specifically for the cases of mergers in the wholesale sector as, for example, in case 17/2010 – *Alliance Healthcare/Medimadeira, Funchalfar*.

The product markets are defined regarding the type of medicine: subject or to not to prescription (ie, over-the-counter), co-paid by the state or not, and type of substance according to the anatomical therapeutic chemical (ATC) classification system, by activity (wholesale, logistic services, equipment, manufacture of medicines). Following the practice of the European Commission, generics are not deemed a relevant market.

In case 72/2005 *Actavis/Alpharma*, the AdC follows the practice of the European Commission, as in other cases, and applies the ATC to help define the relevant market. Normally the third level of the ATC code is sufficient as a starting point to define the relevant market. However, the AdC has specifically stated that sometimes the markets must be defined according to other levels, or it may be necessary to subdivide the ATC3 categories based on other criteria related to the demand of the medicines or to include in the same relevant market products that belong to other ATC3 categories, in particular when the products are considered substitutes by demand.

In fact, in other cases, such as cases 54/2008 – *CSL Limited/Talecris* and 36/2010 – *Bausch & Lomb/Activos Novartis*, the AdC has taken into consideration the ATC4 and ATC5 levels to define the relevant market.

In case 12/2012 *Omega Pharma/GlaxoSmithKline Assets*, the AdC followed the International Consumer Health Classification, in this case the OTC3 level, as suggested by Omega Pharma, since the GSK assets that were to be acquired by the latter regarded mostly over-the-counter medicines and the substitutability between the administration methods is limited.

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

There are cases where generally prohibited practices may be justified. Arguments such as the strengthening of the local or regional research and development activities or efficiency-based arguments can be used to justify certain type of agreements, concerted practices or decisions of associations of undertakings that otherwise would be illegal if they are contributing to improving production or distribution of goods or services or promoting technical or economic progress. Furthermore, in order for such arguments to proceed they must:

- allow the users of these goods or services an equitable part of the resulting benefit;
- not impose on the undertakings concerned any restrictions that are not indispensable to the attainment of these objectives; and
- not afford such undertakings the possibility of eliminating competition from a substantial part of the market for the goods or services at issue.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

A horizontal merger of companies active in the same product and geographical market may be considered problematic when it affects competition by changing the structure of the markets, in particular, when the market share resulting from the merger is significant and can originate in a monopoly or a dominant position.

On the contrary, if there is only a slight overlap in the activity of the merging companies that does not affect the market structure, the AdC does not consider the merger problematic (see case 06/2010 – *Cephalon/Mepha*, where there was a small overlap in only one category of medicines and the market structure was not affected by a higher market share).

In the pharmaceutical sector there has not been a significant product overlap that would affect competition, but the AdC can take into consideration the actual or potential loss of competition.

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

The AdC also assesses the potential effects from the perspective of future pharmaceutical products, as does the European Commission (case 31/2003 – *IDEC Pharmaceuticals Corporation/Biogen Inc* where the AdC quoted case IV/M 737 *Ciba – Geigy/Sandoz*, although in the end it did not consider it to be an overlap).

Therefore, if in a merger one of the merging companies is developing products, they are also taken into consideration for determining the relevant market and whether there is an overlap of products or not. This was the case in the acquisition of OE Holding SA by Recordati SA Chemical and Pharmaceutical Company (case 68/2007 – *Recordati/Orphan Europe*), where the AdC not only took into consideration the market of the existing orphan medicines but also the market of the orphan medicines that were being developed by Orphan Europe. In the end the AdC considered that there is no change in the structure of the market, since there is only a change of the holder of the market share.

This means that the overlap with respect to products that are being developed is treated similarly to an overlap with existing products.

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

The remedies are assessed on a case-by-case basis according to the AdC Guidelines on the Adoption of Remedies. These remedies are first proposed by the involved parties and then assessed by the AdC, which will determine whether they are sufficient to eliminate obstacles to an effectively competitive market.

The Guidelines identify two major groups of remedies: structural remedies and behavioural remedies.

Generally, the structural remedies correspond to the sale of assets (such as licences or trademarks) or groups of assets, including companies or production units.

Behavioural remedies include those that promote or reinforce competition, such as: limits on the parties' actions during the operation (eg, not requiring a certain licence, or not exploiting its own assets); measures to attenuate the client's costs with the change in the merger operation (eg, no customer loyalty schemes); and reduction of the use of exclusive agreements or long duration agreements in the sales of the parties involved in the merger.

However, so far the mergers in the pharmaceutical sector have been authorised without any remedies being required. In the case 44/2003 – *Dräger Medical AG &Co/Negócio de Termoterapia da Hillenbrand (Hill-Rom Air-Shields)*, where the concerned activity is close to the pharmaceutical sector (it concerns neonatal medical equipment), the AdC considered that there would be a significant increase in the market share arising from the merger, affecting the competition structure in Portugal (the second player would be acquiring the market leader). In order to minimise such effects and ensure a competitive market, the AdC authorised the merger, subject to the following five conditions:

- maintaining a second distribution channel for three years;
- maintaining non-discriminatory conditions for three years;
- maintaining a certain type of product as long as there is demand for it in the following three years;
- no direct sale in Portugal for three years; and
- maintaining spare parts for seven years from the production of the last device.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

The acquisition of one or more patents or licences can be subject to reporting requirements, since for the purpose of merger reporting there is a merger (a concentration) when a change of control in the whole or part of one or more undertakings occurs on a lasting basis as a result of, among other things, the acquisition, directly or indirectly, of the whole or part of the assets of one or various other undertakings (including patents or licences). Such change of control results from any act implying the possibility of exercising a decisive influence over the activity of an undertaking on a lasting basis, whether solely or jointly, taking into account, for example, the acquisition of ownership rights, or rights to use the whole or a part of the assets of an undertaking.

The acquisition of one or more patents or licences must be reported if it would result in the acquisition, creation or reinforcement of a market share superior or equivalent to 50 per cent of the domestic market in a specific product or service, or in a substantial part of it; or a market share superior or equivalent to 30 per cent but smaller than 50 per cent of the domestic market in a specific product or service, or in a substantial part of it where the individual turnover in Portugal in the previous financial year, by at least two of the undertakings involved in the transfer of the patents or licences valued at greater than €5 million, net of taxes directly related to the turnover. The acquisition would also be subject to reporting when the turnover of the involved undertakings has reached an aggregate turnover in the previous financial year greater than €100 million, net of taxes directly related to such a turnover, as long as the turnover in Portugal of at least two of these undertakings is above €5 million.

Anticompetitive agreements

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

Articles 9 and 10 of the Competition Legal Regime provide, in line with article 101 of the TFEU, the general framework for assessing whether an agreement or practice can be considered anticompetitive.

Any agreement or practice having as its object or effect the prevention, distortion or restriction of competition in the domestic market, in whole or in part, and to a considerable extent, are deemed anticompetitive and therefore prohibited, in particular those that:

- directly or indirectly fix purchase or selling prices or any other trading conditions;
- limit or control production, markets, technological development or investment;
- share markets or sources of supply;
- apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; or

Update and trends

In the summer of 2016 a new campaign was launched to fight collusion on public tenders. Its aim is to ensure that each company offers its best price without knowing the price offered by its competitors. What happens in some public tenders is that companies divide the market between themselves, and, in some cases, a company offers a lower price for one tender and then another company does the same for another tender. Since the pharmaceutical market is always in the spotlight, in particular because of the weight of costs with medicines and medical devices for the Portuguese National Health System (which all governments try consistently to reduce), it is foreseen that the AdC will pay more attention to the tenders to supply hospitals and other public entities, and will seek to confirm that there was no collusion.

- make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations that, by their nature or according to commercial usage, have no connection with the subject of such contracts.

18 To what extent are technology licensing agreements considered anticompetitive?

There are no guidelines or specific provisions regarding licensing agreements and European regulations are applicable.

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

There are no guidelines or specific provisions regarding co-promotion and co-marketing agreements and European regulations and guidelines are applicable.

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

The agreements that are likely to be an issue normally relate to the pre-determination of prices by pharmaceutical companies, the sharing of sources of supply, or other types of restrictions to the production or development of medicines. However, any agreement that directly or indirectly prevents, distorts or restricts competition is not allowed. Confidentiality provisions would probably not resolve the issue, since in the end, the effect of such agreements on the market will determine whether free competition is affected or not.

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

The vertical restrictions most likely to raise antitrust concerns are those that qualify as hard-core restrictions under the European Commission's Vertical Restraints Block Exemption Regulation.

The AdC considered that the companies Baxter–Médico Farmacêutica Lda, and Glintt – Business Solutions Lda entered into an agreement that fixed the sale prices of unit-dose automatic machines from which vertical constraints to competition arose. The Court of Commerce and the Court of Appeal of Lisbon confirmed the AdC's understanding.

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

To date, there have been no publicly disclosed decisions by the AdC that regard the settlement of patent disputes. However, should such settlements have as their object or effect the prevention, distortion or restriction of competition, they would be in breach of antitrust provisions and, therefore, expose the parties to liability. Patent disputes are subject to arbitration courts.

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

Although this allows pharmaceutical companies to know what their competitors are paying to doctors, no specifics of eventual underlying agreements are disclosed. The type of information to be disclosed concerns solely the amount, the name of the recipient and a brief description of the event that caused the payment (eg, lecture fees, a conference). The transparency measures per se should not affect or increase anticompetitive exchanges of information.

Anticompetitive unilateral conduct

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

A firm with monopoly or market power would be participating in anticompetitive conduct if it were to abuse its position, for example, if it:

- imposes, directly or indirectly, unfair purchase or selling prices or other unfair trading conditions;
- limits production, markets or technical development to the detriment of consumers;
- applies dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- makes the conclusion of contracts subject to acceptance by the other parties of supplementary obligations, which, by their nature or according to commercial usage, have no connection with the subject of such contracts; or
- refuses access to another undertaking to a network or other essential facilities that it controls, when appropriate payment is available, in a situation where the other undertaking cannot act as a competitor of the firm, upstream or downstream, unless the latter can demonstrate that, for operational or other reasons, such access cannot reasonably be provided.

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

The current Competition Legal Regime, unlike the former Competition Act, no longer provides a definition for dominant undertakings. However, the AdC has maintained its understanding that an undertaking is dominant when it has sufficient market power to act independently on the market, with no or limited influence of clients, competitors or any third party.

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

The fact that an undertaking holds a patent does not make it dominant, since other circumstances must be taken into consideration, such as; the relevant market, the existence of substitute products, and the possibility of competing products being developed.

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

In general terms, a simple application for the grant of a patent would not expose the patent owner to liability for an antitrust violation unless this is deemed an abuse of a dominant position.

In the same way, the enforcement of a patent does not make the patent owner liable for an antitrust violation. However, the particular conditions of the case would need to be assessed to establish whether this enforcement is an abuse of a dominant position.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

If the purpose of such strategies is preventing or delaying the entry of generics into the market, this could expose the patent owner to liability for an antitrust violation. On the other hand, if the strategies have objective and reasonable motives that can be demonstrated, there should be no liability for antitrust violation.

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

There is no direct prohibition that prevents a patent holder from marketing its drug as an authorised generic before the expiry of the patent

protection. However, from a competition perspective, this situation may raise some concerns, since it may be deemed to delay or prevent the market entry of generics. Since there is no publicly known decision on a similar case, it is difficult to foresee the position of the AdC on this matter.

Furthermore, medicines are generally prescribed by reference to the active substance, and consumers may choose to buy generic drugs, which are normally less expensive. Therefore, changing to generics may not be an economically attractive solution when the patent protection is still in force.

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

The possible justifications for conduct that would otherwise infringe antitrust rules should not be affected by the specific features of the pharmaceutical sector. The AdC analyses each case, requests opinions when required or deemed relevant, and verifies if the conduct in the pharmaceutical sector may be considered justified.

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

As referred to in the European Commission's reports on the monitoring of patent settlements published between 2013 and 2015, the number of patent settlements has increased in recent years in Portugal. However, it is possible that the reason behind it is the new law that entered into force in 2012 (Law 62/2011). This law basically obliges originators to systematically bring arbitration proceedings against all generics applying for marketing authorisations, since they must initiate arbitration proceedings within 30 days of the publication of a marketing authorisation application by a generic company, otherwise they lose the ability to assert their IP rights.

According to these reports, it is difficult to estimate how many of these settlements would also have been concluded absent the new law, so we do not really know the impact of the EU Pharmaceutical Sector Inquiry in this matter.

Based on the publicly available decisions, one cannot say that the Sector Inquiry has had a significant impact on the enforcement activity of the AdC either.

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

Royal Decree-Law 1/2015 of 2 July 2015, which approved the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices (hereafter the Medicines Act), entered into force on 25 July 2015 and has repealed the former Medicine Act 29/2006, which itself had replaced the Medicines Act of 1990. The Medicines Act governs the authorisation, pricing and financing, marketing, and pharmacovigilance of pharmaceutical products. The procedure of authorisation, registration and dispensation of industrially manufactured medicines for human use is further regulated by Royal Decree 1345/2007.

The Medicines Act regulates price intervention of medicines that are financed by the National Health System (NHS). Although manufacturers are in principle free to determine the prices of their products, the prices of medicines that are reimbursed by the NHS and dispensed in Spain are fixed by the government as maximum prices. Pharmacies, wholesalers and pharmaceutical companies are required to provide the necessary information to allow reimbursement by the pharmacies to wholesalers and pharmaceutical companies of the difference between the regulated price and the free price when medicines included in the NHS financing system are dispensed in Spain through a private prescription. Royal Decree 271/1990 on the reorganisation of price intervention of human medicines further develops the procedure for setting the industrial price of medicines.

Royal Decree 177/2014 regulates the reference price system and homogenous group system. The reference price system is relevant for the financing of medicines, in that it determines the maximum price at which medicines are financed by the NHS. The homogeneous group system is relevant for the dispensation of medicines, in that it determines the price relevant for the application of dispensation and substitution obligations imposed on pharmacists. Royal Decree 177/2014 also regulates certain information systems in connection with the financing and pricing of medicines and medical devices.

The main regulatory body in charge of enforcing the Medicines Act is the Spanish Agency for Medicines and Sanitary Products (AEMPS). The AEMPS is responsible for the evaluation, authorisation and registration of medicines and medical devices in Spain and its main objective is to ensure that the authorised medicines marketed in Spain meet the fundamental criteria of efficacy, safety, quality and accurate information. The AEMPS functionally belongs to the Ministry of Health (MH).

The AEMPS develops a wide range of activities within the framework of medicine evaluation and authorisation for human and animal use: clinical trials, authorisation, continuous monitoring of medicine safety once medicines are on the market, quality control, authorisation and inspection of pharmaceutical companies, supervision of medicine supplies and its supply to the public, certification, control and supervision of medical devices, combating illegal and counterfeit medicines and medical devices, monitoring safety procedures for cosmetics and hygiene products, and providing all relevant information to the public and healthcare professionals.

The Directorate General for the Basic Portfolio of NHS Services and Pharmacy of the MH decides on the inclusion of a medicine in the NHS and manages the reference price system.

The Interministerial Price Commission for medicines of the MH is responsible for fixing prices of medicines.

The 17 Spanish regions have competencies in health and are responsible for the provision of public healthcare services and the enforcement of the regulation governing wholesale and supply, advertising and promotion, etc.

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

Royal Decree 823/2008 sets the margins of wholesalers and pharmacies, as well as certain deductions and discounts applicable to the dispensation of human medicines. Royal Decree 1416/1994 establishes the main rules concerning the advertising of medicines for human use.

Royal Decree 870/2013 regulates the distance sales, through websites, of non-prescription medicinal products for human use.

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

Articles 94 et seq of the Medicines Act, which govern the intervention of pharmaceutical prices by the government, are the most relevant provisions for the application of competition law in the pharmaceutical sector since they are at the origin of the parallel trade phenomenon that has given rise to a proliferation of cases before the European Commission (EC) and the EU Courts (GSK Spain), the national competition authority and the Spanish courts, as will be detailed below. Prices fixed at an artificially low level provide a strong incentive to wholesalers (and even pharmacies) to export medicines into higher-price countries, such as the UK, the Netherlands or Germany.

Articles 67 et seq of the Medicines Act concerning wholesale distribution are also relevant, in particular since wholesalers have relied on them to claim a right to be supplied by pharmaceutical companies.

The provisions of the Act regulating marketing authorisations, the limits to their withdrawal from the market or the NHS, or the obligation to keep the market supplied are also likely to become relevant following the EU's precedent set in the *AstraZeneca* case. In general, the high level of regulation and intervention is relevant to the application of the competition rules, since, together with the NHS's purchasing power, it led the Spanish Competition Authority for Markets and Competition (CNMC) for many years to conclude that pharmaceutical companies are not necessarily dominant, even where their market shares in a given product are high. Although in more recent decisions the authority found that regulation does not necessarily exclude dominance, it nevertheless took this circumstance into account in assessing the existence of an objective justification to allegedly abusive conducts. Legal limitations on advertising and promotion of medicinal products are also relevant to the application of the competition rules and set the framework for voluntary codes of conduct in the industry.

Competition legislation and regulation

4 Which legislation sets out competition law?

The Spanish Competition Act 15/2007 (SCA) and its implementing Regulation 261/2008 establish the essential provisions of national competition law. The EU's competition rules, in particular articles 101 and 102 of the TFEU, are cumulatively applicable to any case that is liable to affect trade between member states of the EU.

The prohibition of anticompetitive agreements is enshrined in article 1 of the SCA, which mirrors article 101 of the TFEU. Article 2 of the SCA prohibits any abuse by one or more undertakings of their dominant position in all or part of the Spanish market and mirrors article 102 of the TFEU. A peculiarity of Spanish law is the possibility of considering acts of unfair competition that distort the conditions of competition in the market as a separate infringement of the SCA, apart from the possibility of pursuing such infringements before the commercial courts under the Unfair Competition Act. Thus, article 3 of the SCA prohibits acts of unfair competition that affect the public interest by distorting free competition. In a decision of 23 January 2014, the CNMC found that the offer by generic producers of discounts to pharmacists above the maximum level permitted by law could infringe article 3 of the SCA, although it dismissed the case on the facts, since no such discounts had actually been offered.

The Spanish merger control regime applies to any concentration in which at least one of the two following circumstances is met:

- a market share of at least 30 per cent is reached or exceeded as a consequence of the concentration in the relevant national product or services market or in a geographical market defined therein. However, even if this threshold is met, the transaction is exempted from the merger control regime when the total turnover in Spain of the target does not exceed €10 million in the last financial year, provided that the individual or combined market share of the parties is below 50 per cent in any of the affected markets in Spain; or
- the aggregated turnover in Spain of all the companies involved in the transaction in the last financial year exceeds the amount of €240 million, provided that at least two of the companies involved have an individual turnover in Spain of at least €60 million.

These thresholds are only triggered if the transaction does not have a 'Community dimension' pursuant to the EU Merger Regulation. When the relevant thresholds are met, a filing to the CNMC is mandatory before the transaction is closed (a notification can be made from the moment there is a concentration project or agreement).

Spanish law only provides for criminal sanctions for antitrust infringements as regards bid rigging in public tenders, which could become relevant in hospital and other public tenders in the pharmaceutical sector. The corresponding provision of the Criminal Code has, however, not yet been enforced in practice. Since October 2015, companies that have participated in bid-rigging cartels in public tenders may be excluded from future tenders under the public procurement rules.

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

In Spain, the central competition authority is the CNMC, which was created by Act 3/2013. The CNMC is the result of a merger, as of 7 October 2013, of the former Competition Authority (CNC) with the regulatory agencies of the network industries (telecommunications, energy, postal, railroad, broadcasting and airlines). The CNMC has two separate decision-making chambers that are in charge of antitrust and regulatory issues, although cases that are relevant to both sections are heard by the Plenary Chamber. Investigations in the area of antitrust are carried out by the Directorate of Competition, which concludes its investigations with a proposal to the Council. The Competition Chamber of the Council then makes a final decision on the case. Regional competition authorities are also competent to investigate and decide on anticompetitive practices (when their scope and effects are limited to the territory of the respective region), although their practical relevance is more limited. Spanish commercial courts are also empowered to apply EU and national competition law regarding anticompetitive practices or abuses of a dominant position.

The CNMC is the only competent body to investigate and clear mergers in the pharmaceutical industry. It has the power to adopt final decisions in merger proceedings, either prohibiting or authorising proposed transactions (with or without conditions). The government may only intervene exceptionally against a decision prohibiting a merger or making its clearance subject to conditions, provided the Minister of Economy decides to refer such cases to the Council of Ministers. In such cases the Council of Ministers has the power to amend the CNMC's decision on relatively broad grounds of public interest, such as national security, public health or the environment. Since the current SCA entered into force in 2007 the government has only used its powers on one occasion (*Antena 3/La Sexta* case). The CNMC analyses whether the proposed transaction may hinder the maintenance of effective competition in the market. The substantive test under the Spanish competition regime is therefore virtually equivalent to the 'significant impediment of effective competition' test under the EU Merger Regulation.

Judicial appeals against resolutions of the Council of the CNMC may be lodged before the Spanish National Court.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

The resolutions of the CNMC may order the cessation of the prohibited conduct; the imposition of specific conditions or obligations, be they structural or behavioural; the removal of the effects of the prohibited practices contrary to the public interest; and the imposition of fines. By way of example, in 1998, the Spanish competition authority imposed fines on various pharmaceutical companies for rigging public vaccine tenders and ordered the companies concerned to cease their collusive practices. In a 2004 decision, it held that the recommendation of the association of pharmaceutical wholesalers (Fedifar) to their members to uniformly react to the introduction of a new pricing scheme by Pfizer amounted to a collective recommendation prohibited by article 1 of the SCA and ordered them to cease that practice, although no fines were imposed.

Infringements of the SCA are classified as minor (including submission of incorrect, misleading or false information, procedural infringements), with a fine of up to 1 per cent of the undertaking's total turnover; serious (infringement of substantive competition rules), with a fine of up to 5 per cent of the total turnover; and very serious (including cartels and the abuse of a dominant position when it is committed by an undertaking that operates in a recently liberalised market, has a market share near monopoly or enjoys special or exclusive rights), with a fine of up to 10 per cent of the total turnover. In addition to these sanctions, a fine of up to €60,000 may be imposed on the legal representatives of the company or on the persons that comprise the management bodies that have participated in the agreement or decision. In May 2016, the CNMC imposed for the first time fines on four executives of adult-diaper manufacturers and their association for participating in a cartel to fix the prices of adult-diapers financed by the NHS and sold through the pharmacy channel. The CNMC may also impose periodic penalty payments of up to €12,000 per day to oblige undertakings to comply with a decision.

A leniency regime was for the first time included in the SCA of 2007 and entered into force in February 2008. This leniency regime offers both total immunity and a reduction of fines in cartel cases, and regulates the procedures for exemptions and reductions of the amount of fines. In June 2013, the CNC published guidelines on its leniency programme.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Any victim of an anticompetitive agreement or conduct by a pharmaceutical company would be entitled to claim damages before the commercial or civil courts, both in follow-on or stand-alone damages actions based on the general provisions of the Spanish Civil Code. In the case of horizontal agreements, typically cartels, both direct and indirect purchasers have standing to claim damages. In a judgment of 7 November 2013 in the *Sugar* cartel case, the Supreme Court recognised that the infringing parties may invoke the passing-on defence against any such claims by direct purchasers. Nonetheless, the burden of proof in that respect is on the infringing party, which will have

to prove that not only the excessive price, but the entire 'damage' (ie, including possible lost profit due to a loss of market share, etc), has been passed on to the next level.

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

The CNMC is competent to launch sector-wide inquires. To date, no sector-wide enquiries have been conducted into the pharmaceutical sector. However, in October 2015 the CNMC published a study on the retail distribution of pharmaceutical products, which analysed the restrictions of competition stemming from the current regulatory framework (eg, restrictions concerning the number of pharmacies, the distance between them) and proposed several measures to increase competition. The CNMC also published a report on the Draft Royal Decree Law that approves the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices (the future Royal Decree Law 1/2015), and a report on the Draft Royal Decree on financing and pricing of pharmaceutical and healthcare products. In November 2016, the CNMC published a report on the Draft Royal Decree implementing the new Patent Act. The Report analyses possible anticompetitive use of patents, particularly in the pharmaceutical sector, through collusive practices (patent settlements) or unilateral conduct (patent thicket, product hopping, abuse of litigation, abuse of regulatory proceedings, etc) and invited the legislator to take these practices into account in designing a patent system that reconciles promotion of innovation and defence of competition.

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

Under the Spanish Civil Procedure Act, legally constituted consumer and user associations have standing to defend the rights and interests of their members and of the association in court, as well as the general interests of consumers and users. Trade associations and consumer groups also have standing to file complaints before the CNMC and have the right to be consulted on the approval of any new regulation.

The Spanish Association for the Pharmaceutical Industry (Farmaindustria), Fedifar and the Spanish Federation of Pharmacists have in the past filed complaints before the Spanish competition authority against alleged anticompetitive practices or abuses of a dominant position. The European Association of Euro-Pharmaceutical Companies has also brought complaints against pharmaceutical companies related to parallel trade issues.

Review of mergers

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

Mergers between two pharmaceutical companies are analysed on a case-by-case basis. If the specific features are relevant for the competition analysis they will be taken into account. Certain aspects have been referred to widely: with respect to entry barriers, the most important for the manufacturing and marketing of medicines is pharmaceutical regulation, as well as patents and the procurement of raw materials, among others. In addition, the strong countervailing buyer power is also relevant since the Spanish public authorities, in particular the NHS, are the main customers of pharmaceutical companies.

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

The CNMC has adopted the same approach as the EC when assessing the market definition in the pharmaceutical sector. Regarding product market definition, the CNMC has in general defined it on the basis of the third level of the ATC classification that allows for a regrouping of pharmaceuticals based on their therapeutical indication, although on occasion it has relied on other ATC levels, including ATC5. In a decision of 13 February 2014, in the context of a possible abuse of a dominant position by Pfizer, the CNMC defined the market based on the fourth ATC level, following the EC's more recent practice to define relevant markets more narrowly in abuse cases. In accordance with the EC's practice, the geographic market is usually defined as national because of its regulation.

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

The criteria to be taken into account in merger reviews under the SCA include the economic efficiencies derived from the concentration, and, in particular, the contribution that the concentration may make to improving the production or marketing systems, and to business competitiveness, and the extent to which these efficiencies are transferred to the intermediate and ultimate consumers, specifically in the form of a larger or better supply and of lower prices.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

When assessing mergers, the Spanish competition authority analyses whether a product and geographical overlap may hinder the maintenance of effective competition in the market. The first elements taken into account when analysing a merger are the structure of the relevant markets and the position of the parties therein. However, under certain circumstances, high market shares are not necessarily equivalent to a hindrance of effective competition in the market and concentrations resulting in high market shares have been authorised in a number of cases (for instance, in July 2016, the CNMC authorised a concentration between two manufacturers of radiopharmaceuticals, giving rise to market shares of 70 to 80 per cent).

Other elements taken into account when analysing a merger are the existence of actual or potential competitors inside or outside the national market, the possible alternatives for suppliers and consumers and their access to supply sources, the existence of barriers to entry into the market, the evolution of supply and demand, the negotiating power of supply and demand and their capacity to compensate the position of the parties to the transaction in the market, and the economic efficiencies derived from the operation, in particular the contribution of the merger to the development of production or marketing systems, the competitiveness of the industry and the proportion in which those efficiencies are transferred to consumers through a better or wider offer and lower prices.

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

In order to identify overlaps, the CNMC usually considers actual market shares. An example of potential competition overlaps can be found in the telecommunications sector, where the Spanish competition authority opposed Telefónica's acquisition of Iberbanda, given that the latter was developing a competing technology.

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

Remedies may be either structural or behavioural, although as in the EU the CNMC has a certain preference for structural remedies. The CNMC closely monitors the compliance by the parties with any remedies that have been made binding on them and, indeed, the remedies as such most usually include reporting obligations to the CNMC on the compliance with the conditions imposed.

A (rare) example of a concentration in the pharmaceutical sector authorised subject to conditions is the *Cofares/Hefame* case, a concentration of two wholesalers active in the distribution of pharmaceutical and para-pharmaceutical products in Spain and controlled by cooperatives of pharmacies. The Spanish competition authority held that minimum purchase obligations of the members of the two pharmacy cooperatives and minimum membership terms amounted to a barrier to entry for new wholesalers. The potential threat to competition was high given the large market share that the merged entity would have. Thus, the merger was approved under the conditions that the minimum purchase requirement was lowered from 30 per cent to 25 per cent, and the minimum term of membership was reduced from five years to one year.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

The acquisition of one or more patents or licences would be considered as a concentration for merger control purposes, provided that a turnover can be attributed to the asset in question.

Anticompetitive agreements

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

Article 1(1) of the SCA prohibits all agreements, collective decisions or recommendations, or concerted or consciously parallel practices, that have as their object, have, or potentially have the effect of preventing, restricting or distorting competition in all or part of the Spanish market. Agreements that would otherwise be caught by article 1(1) of the SCA may be exempted if they generate efficiencies that benefit consumers, do not impose restrictions that are not indispensable for the attainment of these efficiencies and do not eliminate competition on the relevant market. Pursuant to the SCA, EU block exemption regulations also apply in the national context (ie, to agreements that do not affect trade between member states). Although article 1 of the SCA closely mirrors article 101 of the TFEU, it differs from the latter in that it explicitly prohibits 'conscious parallel practices', a form of concerted practice that has also been developed in the ECJ's case law. The Spanish competition authority defined this practice in its 2001 decision in *Laboratorios Farmacéuticos* as 'a harmonised behavior by various market participants that is not the result of an express or tacit agreement, but the result of carrying out their respective actions with the purpose of avoiding disharmony'. In the *Vaccines* case of 1998, the CNMC relied on mere incidental evidence for its finding of a concerted bid-rigging practice. In October 2015, the CNMC closed proceedings against several pharmaceutical companies and the Spanish Federation of Health Technology Companies for alleged information exchanges and price-fixing agreements, without deciding on the substance, since the alleged infringements were time barred. In a decision of 12 January 2016, the CNMC dismissed a complaint by a regional health authority against the Ministry of Health, Farmaindustria and several pharmaceutical companies, in relation to an alleged concerted practice not to participate in a tender organised by the regional authority to select pharmaceutical products to be dispensed in pharmacies in case of prescription by active substance and certain measures taken by the Ministry against the initiative of that authority. According to the CNMC, the conduct of the Ministry of Health fell outside the scope of competition law since the Ministry acted as a public authority and the conduct of the pharmaceutical companies could be explained by the legal uncertainty concerning the legality of the tender organised by the regional health authority, the competence of which to organise such a tender had been challenged by the Spanish government before the Constitutional Court.

With regard to collective recommendations, in its 2009 decision *Productos Farmacéuticos Genéricos*, the CNMC fined four pharmaceutical associations for making collective recommendations in an attempt to harmonise the economic behaviour of pharmacists against Laboratories Davur. However, in a judgment of 24 October 2014 the Supreme Court quashed this decision, holding that the communications sent by the associations to pharmacists were not aimed at harmonising their behaviour in relation to certain price cuts announced by Davur, but essentially provided information on the legislation in force and an interpretation of the legal criteria to determine which product pharmacists are required to dispense (not the cheapest product but the one with the 'lowest price' included in Annex 5 to Order 3997/2006). In a 2009 decision, confirmed by judgment of the Supreme Court of March 2015, the CNC found that a regional health authority and the Council of Official Associations of Pharmacists had infringed article 1 of the SCA by agreeing that the Official Associations of Pharmacists would establish which pharmacies would supply, in rotation, public and private medico-social centres, which amounted to market sharing. In monitoring the compliance with the 2009 decision, the CNMC found in a decision of September 2014 that certain medico-social centres were implementing a system of rotating shifts between the pharmacies supplying them, but held that the implementation of this system was the result of a unilateral decision of the centres, therefore being outside the scope of article 1 of the SCA. In a decision of November 2016, the CNMC found that there was no evidence of a concerted practice between pharmacies of the Murcia Region, through the Official Association of Pharmacists of that Region, to establish a similar system of rotating shifts, but also ordered the investigatory body to continue monitoring, since other possible forms of coordination between pharmacies had not been analysed during the investigation and the regional legislation in force promoted the adoption of agreements between pharmacies.

18 To what extent are technology licensing agreements considered anticompetitive?

Technology licensing agreements are assessed under Commission Regulation (EU) No. 316/2014 of 21 March 2014 on the application of article 101(3) of the TFEU to categories of technology transfer agreements (TTBER), which is applicable mutatis mutandis to article 1 of the SCA. The TTBER provides a general exemption for two-party technology transfer agreements involving patents, know-how or software copyrights if the parties' market share in any relevant product market or technology market does not exceed 20 per cent (combined, for competitors) or 30 per cent (each, for non-competitors). However, the TTBER exemption generally does not apply to agreements that include restrictions on price, limits on output, market-allocation provisions, or restrictions on the licensee's ability to conduct research or exploit its own technology.

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

There are no precedents of co-promotion and co-marketing agreements analysed by the CNMC. While co-promotion agreements are less problematic from an antitrust perspective because the parties are usually not competitors in the manufacturing of the product in question, co-marketing agreements may give rise to horizontal price fixing or market sharing and should, therefore, be carefully assessed. Nevertheless, following the *Johnson & Johnson/Novartis* decision of the EC, co-promotion agreements might be found to infringe article 1 of the SCA or article 101 of the TFEU if they are entered into by an originator and a generic producer to delay generic entry.

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

Of particular concern to the CNMC since the entry into force of a new Competition Act in 2007 have been the activities of industry associations, and many decisions imposing fines have been adopted. They relate to information exchange schemes – which must not lead to an exchange of individual, non-historic data, but rather limit themselves to the exchange of aggregated historical data – collective recommendations, such as those condemned in the above-mentioned *Fedifar* and *Davur* decisions (the latter was quashed by the Supreme Court); and codes of conduct, which must not limit competitive behaviour, such as advertising, beyond what is indispensable to achieve legitimate deontological objectives. In its decision of 23 January 2014 (*Especialidades farmacéuticas genéricas*) the CNMC found that the declarations made by the president of a generic manufacturer association from his personal Twitter account, concerning generic producers who offered aggressive price reductions to the NHS, were not capable of significantly affecting competition, given their limited reach and short duration. The recent judgment of the Supreme Court in the *Davur* case, as well as other judgments that annulled decisions of the competition authority on collective recommendations in other sectors, might lead the authority to raise the standard for a finding of an illegal collective recommendation.

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

Any limitation of parallel trade in vertical agreements is likely to raise competition concerns. After GSK Spain notified a dual-pricing scheme to the EC in 1998, the ECJ held on appeal, on the one hand, that any limitations of parallel trade, also in the pharmaceutical industry, were restrictions of competition 'by object', and, on the other, that the Commission had been wrong to reject the exemption sought by GSK for that restriction under article 101(3) of the TFEU. The litigation at EU level was accompanied by a myriad of cases before the Spanish competition authority and the administrative courts, which were eventually all

Update and trends

After the CNMC's *Pfizer* decision of 19 January 2017 and potential appeals against it by parallel traders, it is likely that parallel trade will remain a hot topic in the Spanish pharmaceutical sector.

decided in favour of GSK. Following these precedents, pharmaceutical companies started adopting free-pricing systems instead of the usual supply quota systems operated under the *Bayer-Adalat* case law of the European Courts. Under these schemes the manufacturers only set one free price, which applies to any situation not leading to a reimbursement under the public price intervention scheme described above. Thus, if a medicine is financed by the NHS and dispensed in Spain, the regulated price set by the state will apply, while medicine exports are subject to the (higher) free price set by the manufacturer.

The EAEPC and a Spanish wholesaler complained against this new pricing scheme to the CNC, which dismissed these complaints, holding that there was no dual pricing and therefore no restriction of competition. On appeal, the Spanish National Court quashed these decisions in two judgments of 2011 and 2012, holding that the scheme limited parallel trade and therefore had to be assessed pursuant to the *GSK Spain* case law of the ECJ, which qualifies agreements restricting parallel trade as restrictions of competition by object. It also held, however, that under the same case law, the agreements might qualify for exemption under article 101(3) of the TFEU, but that the CNMC had to pronounce itself in this respect. The 2011 and 2012 judgments of the Spanish National Court were confirmed by the Supreme Court in two judgments of 3 December 2014 and 4 March 2016. In particular, in the judgment of 3 December 2014 the Supreme Court rejected that there had not been an 'agreement' for the purposes of article 101 of the TFEU between Pfizer and its wholesalers, since Pfizer had concluded supply contracts with each wholesaler, which included the 'free pricing' provisions. According to the Court, these clauses have as their main object to impede or restrict parallel exports of pharmaceuticals into other member states of the EU. The ruling recalls that the judgment of the Spanish National Court rests on the ECJ's ruling in *GSK Spain*, where the Court held that the application of different prices to financed medicines dispensed in Spain and higher prices to exported medicines, amounted to a restriction of competition contrary to article 101(1) of the TFEU. Further to the Supreme Court's judgment of 3 December 2014, in March 2015 the CNMC started infringement proceedings against Pfizer in relation to a possible restrictive practice consisting of establishing supply contracts liable to impair parallel trade. In its decision of 19 January 2017, the CNMC held that the pricing system established by Pfizer does not infringe Article 1 SCA. First, the CNMC found that Pfizer did not establish a dual pricing system with the object of restricting parallel trade, but only set a free price, which is then replaced by the regulated price when the requirements for the application of the latter are fulfilled. According to the CNMC, Pfizer's behaviour is not an autonomous behaviour, due to state intervention, and cannot therefore be deemed to infringe competition law. Secondly, the CNMC found that the GSK case law cannot be applied by analogy to the Pfizer's case, since the applicable legal framework is different. According to the CNMC, the establishment of a dual pricing system by GSK was the result of a voluntary decision by GSK, who made an extensive interpretation of the legislation then in force that required the application of the regulated price to all financed medicines sold in Spain (independently of where they were dispensed). In the new legal framework that entered into force in January 2000 – in which the regulated price no longer applied to all sales of financed medicines in Spain, but only to sales of financed medicines actually dispensed to patients in Spain – the establishment by Pfizer of different prices for the same medicine merely complied with the applicable legislation, which implicitly introduced the existence of two different prices for the same product.

Similarly, in a judgment of 7 December 2015, the Provincial Court of Madrid held that the *GSK Spain* case law was not applicable to the free-pricing system of a pharmaceutical company, essentially arguing that the legal framework of the Medicines Act had changed since the *GSK Spain* case and that the scheme did not amount to dual pricing, but rather was the result of a unilateral decision of the pharmaceutical company. In the same judgment, the Audiencia Provincial held that the restructuring of the distribution system of that pharmaceutical company, which resulted in a reduction in the number of wholesalers, was objectively justified since it pursued the objective of increasing efficiency and therefore could not be held abusive, even assuming that the company were dominant.

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

No cases have been decided yet, but the CNMC is likely to apply the same principles developed in the EC's *Lundbeck* decision, confirmed by the judgment of the General Court of 8 September 2016 (ie, agreements whereby an originator company makes payments or gives other benefits to generic companies for delaying the launch of a generic challenging the originator's patent (reverse payment patent settlement) may be deemed to infringe article 1 of the SCA or article 101 of the TFEU). In a decision of 18 June 2014 (*Citicolina*), the CNMC dismissed for lack of evidence an anonymous complaint against a pharmaceutical company for delaying and impairing generic entry by means of, inter alia, payments made to potential competitors in exchange for not entering the market. In the same decision, the CNMC ordered the Competition Directorate to monitor future developments in the market and, in particular, the granting of marketing authorisation of the active substance at issue and the actual marketing of the authorised products.

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

Taking into account, in particular, the type of data to be published, the level of aggregation and the frequency of publication, transparency obligations assumed by pharmaceutical companies should not raise competition concerns.

Anticompetitive unilateral conduct

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

Under article 2 of the SCA, any abuse by one or more undertakings of their dominant position in all or part of the national market is prohibited. Dominance is not in itself prohibited, but if an undertaking holds a dominant position it has a special responsibility to ensure that its conduct does not distort competition. Abusive behaviour consists mainly of exclusionary conduct (predatory pricing, exclusive dealing, refusal to supply, tying) and exploitative abuses (excessive pricing, discrimination between customers). In its 2003 *Cofarca* decision, the CNMC fined a cooperative of pharmacists for abusing its dominant position in a regional market of wholesale distribution of medicines by imposing minimum purchase obligations on its members. In December 2015 the CNMC initiated infringement proceedings against IMS Health for a possible infringement of article 2 of the SCA and article 102 of the TFEU through the establishment of contractual conditions with Spanish pharmaceutical wholesalers that would allegedly impair or impede the entry of new competitors in the market. In February 2017, the CNMC initiated infringement proceedings against Aspen and its Spanish distributor Deco Pharma, for alleged abusive practices by Aspen (refusal to supply and application of excessive prices) and an alleged agreement between Aspen and Deco Pharma to limit distribution.

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

The market share is the first element analysed when assessing dominance together with other factors, such as the market shares of competitors, historical volatility of such market shares, entry barriers, countervailing buyer power and the level of regulation, a key element in the pharmaceutical sector.

For many years, the Spanish competition authority has held that in view of the heavy regulatory burdens and in particular the intervention of prices by the public authorities and the buyer power of the NHS, pharmaceutical companies are not in a dominant position even if their market share in a given product market is clearly above 50 per cent. These findings have been made in the context of complaints against manufacturers for refusing to supply extraordinary quantities of pharmaceuticals to wholesalers. More recently, the authority no longer seems to exclude

the possibility of dominance. In particular, in the *Sedifa-Grufarma* case, the CNC stated that the fact that the activity of pharmaceutical companies is regulated and their ability to act may be limited in certain aspects does not impede a possible finding of dominance (which was not established in the case at issue). In the *Pfizer/Xalatan* case, the CNMC found that Pfizer held a dominant position because of the exclusivity granted by the patent on the latanoprost active substance.

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

As indicated, in the *Pfizer/Xalatan* case, the CNMC found that Pfizer held a dominant position because of the exclusivity granted by the patent on the latanoprost active substance. However, a patent holder should be held dominant only if no substitutes of the product in question exist on the relevant product market. In the above-mentioned judgment of 7 December 2015 the Provincial Court of Madrid refused to find dominance based only on ownership of a patent.

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

There are no precedents in Spain where an application for a grant of a patent has been considered as an abuse. In the *Pfizer/Xalatan* decision of 13 February 2014, the CNMC closed the proceedings initiated against Pfizer in relation to the prolongation of the Xalatan's patent, holding that no infringement of article 2 of the SCA and article 102 of the TFEU had been proved. In its reasoning the CNMC referred to the *AstraZeneca* judgment (C-457/10), although it did not expressly invoke the differences between Pfizer's and AstraZeneca's respective conducts to conclude that Pfizer's conduct was not abusive. The CNMC also seems to have taken into account the fact that Pfizer did not send communications to Spanish authorities and generic producers concerning the prolongation of its patent, it only initiated judicial proceedings against one generic producer that it then withdrew and generic products were marketed in Spain during the period of the patent's prolongation. Interestingly, the CNMC's investigation was prompted by an investigation of the Italian competition authority concerning essentially the same product and similar practices, which, however, terminated with an infringement decision confirmed by the Italian State Council.

Regarding the enforcement of patents by bringing actions for patent infringement, in the 1998 *Wellcome* case (R 315/98), the Spanish competition authority found that the criminal proceedings for patent infringement initiated by Wellcome against the generic producer Combino Pharm and the company that manufactured generics on behalf of Combino Pharm were aimed at protecting alleged patent rights that Wellcome deemed infringed by these two companies. It found that this practice could not be deemed as an unfair competition act by reason of the publicity given by the press to the proceedings at issue and in any event did not appreciably affect competition contrary to the public interest. In the 2011 *Novartis* decision, the CNC closed proceedings against Novartis for an alleged abuse of a dominant position by bringing an action for patent infringement against the generic company Actavis, which it subsequently withdrew. The CNC held that Novartis' legal suit and request for preliminary measures could a priori seem excessive or disproportionate in light of Actavis' conduct (Actavis had obtained marketing and price authorisation for a generic product), but there were no indications of an abusive exercise of the right to judicial protection, to the extent that Novartis' withdrawal of the legal suit was not the result of an agreement or settlement between the parties.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

There are no decisions of the Spanish competition authority on life-cycle management strategies. However, the *AstraZeneca* judgment (C-457/10) is likely to be followed as a precedent. The above-mentioned *Pfizer/Xalatan* case also provides a first example of the CNMC's position towards practices aimed at prolonging patent protection.

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

Given that Spanish regulation imposes prescription by active substance, obliges pharmacists to dispense the medicine with the lowest price and therefore excludes originator drugs if they do not match the lowest price, there are no incentives for a patent holder to license or market such generics before the expiry of its patent.

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

For many years, the Spanish competition authority and courts have recognised that the specific features of regulation may exclude the existence of dominance on the part of pharmaceutical companies, although more recently in the *Sedifa-Grufarma* case the CNC did not exclude the possibility of dominance on this basis. However, in the same case the CNC held that the allegedly abusive conduct – refusal to supply to certain wholesalers – should be assessed taking into account the legal and economic context, in particular, the partial liberalisation of the price of medicines following the 2006 Medicines Act, which prompted a restructuring of the pharmaceutical companies' distribution networks for efficiency reasons. The CNC finally held that even assuming dominance, the conduct at issue was not abusive since it was objectively justified by this restructuring aimed at increasing efficiency. In its decision of 19 January 2017, the CNMC relied on the state's intervention on prices of medicines to come to the conclusion that Pfizer's pricing system did not infringe article 1 SCA.

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

So far there has been no increase in these types of cases following the EU Sector Inquiry.

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The primary 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 Licence 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.

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.

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 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.

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

Aside from the price and profit-margin ceilings, the regulatory framework for pharmaceutical products is not specific or directly relevant to the application of Turkish competition laws to the pharmaceutical industry. The industry is subject to the general competition law rules, barring any judicial precedents that take account of the sector-specific aspects of the industry.

Competition legislation and regulation

4 Which legislation sets out competition law?

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

- Block Exemption Communiqué No. 2017/3 on Vertical Agreements and Concerted Practices in the Motor Vehicle Sector;
- Communiqué No. 2017/1 on the Increase of Minimum Administrative Fines Specified in Paragraph 1 of Article 16 of the Law No 4054;
- 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;
- 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; 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;
- 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 (Draft Law) was submitted to the Grand National Assembly of Turkish Republic on 23 January 2014. In 2015, the Draft Law became obsolete due to the general elections in June 2015. As reported in the 2015 Annual Report of the Competition Authority, the Competition Authority has requested the re-initiation of the legislative procedure concerning the Draft Law.

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

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

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 in order 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 damages.

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.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

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 due 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; *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.

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

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 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.

9 To what extent do non-government groups play a role in the application of competition rules 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

10 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; *Zentiva/PPF*, 9 July 2008, 08-44/608-233).

11 How are 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, *Reckitt Benckiser*, 7 July 2015, 15-28/344-114; *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 ATC4 classifications or has opted for a narrower market definition than the ATC3 classification (*Roche*, 16 November 2016, 16-39/642-288; *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.

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

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 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market 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/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; *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.

14 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 its capacity in 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 Competition 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.

15 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; *DSM NV/Roche*, 11 September 2003, 03-60/730-342; *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. In order for behavioural remedies to be accepted alone, such remedies must produce results as efficient as divestiture, such as:

> *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).

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

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.

Anticompetitive agreements

17 What is the general framework for assessing whether an agreement or 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) 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'.

18 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 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 anticompetitive. Hard-core 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.

19 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; *Sandoz/Eli Lilly*, 2 August 2007, 07-63/776-282).

Update and trends

The past year did not see any ground-breaking cartel cases or record fines for cartel activity in the pharmaceutical sector. In fact, there has been an easily detectable decline in the number of cartel cases. Most of the full-fledged investigations did not result in monetary fines against the defendants. 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.

Most notably, there have been changes in the Competition Board's seating as 2016 saw three members of the Board being replaced.

As mentioned above, there is a potential draft law proposal pending. 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. In 2015, the Draft Law became obsolete due to the general elections in June 2015. As reported in their 2015 Annual Report, the Competition Authority has requested the re-initiation of the legislative procedure concerning the Draft Law.

In terms of recent landmark case law, the Board recently concluded that six cement companies operating in the Aegean region of Turkey violated Article 4 of the Competition Law by sharing sales territories and increasing resale prices in collusion in the Aegean region (14 January 2016, 16-02/44-14). The decision is pertinent in that the Board classified the case as 'cartel' and defined cartels in a manner that encapsulates both agreements and concerted practices. The Board fined the cement producers by a total of approximately 71 million Turkish lira. The fines ranged between 3 per cent and 4.5 per cent of each company's 2014 annual turnover. These fines were relatively high in the Turkish jurisdiction in terms of turnover percentage.

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.

20 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.

21 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; *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, 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; *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; *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.

22 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.

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

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

24 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.

25 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).

26 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 25.

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.

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

There 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.

There is no specific precedent or case law on this matter. Theoretically speaking, the answer to question 27 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.

28 Can certain life-cycle management strategies also expose the 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.

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

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.

30 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

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hospital inventories stocked (eg, *Roche*, 16 November 2016, 16-39/642-288; *Roche*, 13 October 2016, 16-33/569-247; *Daiichi*, 8 September 2016, 16-30/504-225).

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

Not applicable.

Ukraine

Alexey Pustovit

Asters

Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The relevant legislation includes the following:

- Law on Medicines 1996;
- Law on Legislative Fundamentals in Health Care 1992;
- Law on Licensing of Certain Types of Economic Activity 2015;
- Law on Advertising 1996;
- Resolution of the Cabinet of Ministers of Ukraine (CMU) Approving the Procedure for State Quality Control of Medicines Imported to Ukraine, No. 902 2015;
- Resolution of the CMU on State Regulation of Prices for Medicines No. 862 2016;
- Resolution of the CMU on Reimbursement of the Cost of Medicines No. 863 2016;
- Resolution of the CMU Approving the procedure for State (Re-)registration of Medicines and State (Re-)registration Fee, No. 376 2005;
- Resolution of the CMU on the Measures for Stabilisation of Prices for Medicines and Medical Devices, No. 955 2008;
- Resolution of the CMU on the Notification of Changes in Wholesale Prices on Medicines and Medical Devices, No. 240 2014;
- Resolution of the CMU on Certain Issues of State Regulation of Prices for Medicines and Medical Devices, No. 333 2009;
- Resolution of the CMU on the Implementation of a Pilot Project Regarding the Introduction of State Regulation of Prices for Medicines for Treating Persons with Essential Hypertension, No. 340 2012; and
- Decree of the Ministry of Health of Ukraine (MHU) Approving the Procedure for Expert Examination of Medicines' Registration Materials which were Submitted for State (Re-)registration and Expert Examination of Materials on Amendments to Registration Materials within Registration Certificate Validity Term, No. 426 2005.

The regulators entrusted with enforcing these rules include:

- the Cabinet of Ministers of Ukraine;
- the Ministry of Health of Ukraine;
- the State Administration of Ukraine on Medicinal Products;
- the State Expert Centre of the Ministry of Health of Ukraine;
- the Antimonopoly Committee of Ukraine; and
- the State Inspection of Ukraine on Consumer Rights Protection.

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

- The Order of the MHU Approving the Licensing Terms for Manufacturing, Wholesale and Retail of Medicines, No. 723 2011;
- The Order of the MHU Approving the Licensing Terms for Conducting of Economic Activity regarding Import of Medicines, No. 143 2013;
- The Order of the MHU Approving the Procedure of the Quality Control of Medicines in Retail and Wholesale Trade, No. 677 2014;
- The Order of the MHU Approving the Procedure of the Certification of Enterprises, which are the Wholesalers (Distributors) of Medicines, No. 421 2005;
- Guidelines of the MHU 42-5.0:2014 – 'Medicines. Good Distribution Practice'; and
- Guidelines of the MHU 42-5.1:2011 – 'Medicines. Good Storage Practice'.

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

The above legislative acts mainly regulate technical requirements. The Resolutions of the CMU regulating price-related issues are possibly the most relevant, in particular, by setting maximum margins for selected medicines.

Competition legislation and regulation

4 Which legislation sets out competition law?

Dominance, anticompetitive conduct and mergers are regulated by the Law on Protection of Economic Competition 2001, while unfair competition issues are addressed in the Law on Protection against Unfair Competition 1996.

Competition legislation is enforced by the Antimonopoly Committee of Ukraine (AMC), which has quite broad powers that cover mergers, arrangements and practices in the pharmaceutical sector. Its activity is regulated by the Law on the Antimonopoly Committee of Ukraine 1993.

The AMC issues regulations and guidelines comprising a substantial part of the national competition legislation. The most relevant are:

- the Regulation on the Procedure for Filing Applications with the AMC for Obtaining its Approval of the Concerted Practices of Undertakings (the Concerted Practices Regulation) 2002. The document clarifies the procedure for obtaining concerted practices approvals and requirements to notifications;
- the Regulation on the Procedure for Filing Applications with the AMC for Obtaining its Prior Approval of the Concentration of Undertakings (the Merger Regulation) 2002. Similar to the Concerted Practices Regulation, the document sets the procedure and requirements for merger applications;
- the Methodology for Establishment of the Monopoly (Dominant) Market Position of Undertakings (the Monopoly Methodology) 2002, which contains rules on market definition and tests for dominance and collective dominance;
- the Resolution on the Standard Requirements to Concerted Practices of the Undertakings for their General Exemption from the Requirement to Obtain Prior AMC Clearance (the General Exemption Regulation) 2002, which sets safe harbours for agreements between undertakings; and
- the Resolution on the Standard Requirements to Concerted Practices of the Undertakings concerning Joint R&D or Development and Engineering Works 2012 (the R&D Regulation).

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

There is no special authority in charge of competition issues in the pharmaceutical sector. The AMC conducts investigations and decides pharmaceutical cases and mergers following general rules and procedures.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

These can be split into interim measures and decisions. During a case investigation the AMC can request that an undertaking refrain from certain practices if, in the authority's opinion, these practices may qualify as a violation of the competition laws. The AMC may also obligate an undertaking to perform certain actions that are required to ensure the rights and interests of third parties.

Where the AMC identifies that conduct or agreements have characteristics of violation of the competition laws, it may also issue recommendations to cease such practices without opening a case investigation. If the undertakings comply with the recommendations and, where applicable, take measures to remove the AMC's concerns, it can avoid the case investigation and sanctions that would be problematic, should the AMC complete the investigation and issue a statement of objection.

Following the case investigation, the AMC can issue a decision containing an order to bring the violation to an end and also to eliminate the consequences of the violation.

It should be noted, however, that often the AMC's recommendations and decisions lack precision and the addressees face difficulties in understanding what exactly in their conduct raises competition concerns and how best to resolve the problematic issues. For this reason, remedies usually require follow-up negotiations with the AMC.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Yes, private parties can lodge complaints with the AMC. If the AMC finds that certain conduct raises competition concerns, it may impose remedies. For details on the remedies, see question 15.

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

Yes, the AMC does this quite regularly. Focus of the inquiries varies from year to year, recent hot topics are:

- retroactive discounts (in the AMC's view any discount should be passed downwards and should result in lower prices for end customers);
- transparency of conditions offered by pharmacies (the AMC wishes to ensure non-discriminatory conditions);
- payments to pharmacies for various marketing services; and
- inadequate pricing practices.

Most of the concerns relate to abuse of dominance where the AMC tends to define markets very narrowly, both by product and geography. See question 11.

As the result of most of the sector inquiries the AMC issued recommendations; in some cases it opened investigations into suspected violations, with a few cases resulting in fines. The vast majority of fining decisions concerned abuse of dominance. The AMC also often requests or suggests remedies in its decisions, usually to refrain from increasing prices.

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

The AMC welcomes cooperation with such groups, but it is mainly limited to an exchange of opinions. Recently, the AMC made an attempt to find effective ways to resolve some of the most problematic issues in marketing in the pharmaceutical sector by creating a working group with representatives of NGOs.

As regards enforcement, complaints can be lodged by parties suffering from an alleged violation that appreciably limits the mechanisms available to the groups to influence the AMC. However, various round tables and public discussions are usually taken into account by the AMC, and there have been cases where the issues raised by the groups resulted in investigations and decisions.

Review of mergers

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

There are no sector-specific rules in Ukraine. Given that pharmaceutical deals are normally large-scale, a great deal of the mergers reviewed by the AMC are not domestic transactions. Still Ukrainian merger control rules capture many foreign-to-foreign transactions and there have been many decisions in such cases.

The latest trends show that the AMC – by publishing short notices on its website and sending information requests to selected respondents – actively encourages third parties to express their opinions with respect to notified mergers. From a competition analysis perspective, the effectiveness of the new approach is questionable; it also makes the review process more complex and less predictable for the notifying parties, as the law is generally silent as to what extent such third parties shall be heard, and scope of their involvement is at the AMC's discretion. Judging from past cases, the notifying parties may need to address negative opinions that are not always substantiated (eg, the authority may not have sufficient resources to do a fast and proper analysis of such responses).

Another issue is that the AMC approach to defining the relevant markets and assessing possible effects on competition is still developing, and may vary from case to case.

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

Historically, the AMC reviewed most mergers referring to ATC classification. In most cases it used ATC level 3 as a starting point; recent merger cases show that the authority tends to examine at ATC 4 or even ATC 5 level. Over the last year the AMC has conducted many sector inquiries that led to alternative market definitions. While the AMC continues to predominantly use ATC3 in merger cases, in other cases it would rather initiate an in-depth substitutability analysis.

The AMC often relies on various scientific studies and opinions of the competent Ukrainian associations and institutes. Where switching to an alternative product is problematic (eg, because of the established practice or other reasons why the procuring public authorities would normally stick to specific brands), the AMC is likely to consider such product as a separate market, even though there could be substitutes at the same ATC level. Other factors that are often seen as differentiating between products are, for example, galenic form, dosage or even the price. There have been cases where competing products were each considered as a separate product market because they were marketed under different brands.

As regards geography, the AMC would often consider the national market. In mergers it may also take a wider approach and look at the market more globally (in particular as regards APIs), especially when it comes to overlaps or claimed efficiencies.

For mergers involving distributors and pharmacies in particular, the markets may be defined much more narrowly. In many abuse of dominance cases pharmacies were considered as having a dominant position on selected streets or other small areas. Needless to say, such an approach is heavily criticised.

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

In mergers, efficiencies may be taken into account, but they would not outweigh serious competition concerns at the AMC review stage. The legislation, however, provides for the possibility of seeking CMU clearance of a transaction prohibited by the AMC. This procedure is very complex and rarely used (there are no precedents in the pharmaceutical

sector), but the efficiencies or other advantages should be taken into account by the CMU.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

There are two tests for assessment of mergers in Ukraine. The merger can be prohibited if it either results in monopolisation or substantial restriction of competition on the market. There is no established practice on assessing the competition concerns raised by a merger, but historically the AMC analysed whether such merger may lead to monopolisation on the relevant market.

Monopolisation is defined as obtaining or strengthening of a dominant position without further elaboration; the AMC considers any increase in the market share above the dominance threshold (irrespective of the increment) as monopolisation. Dominance is presumed to exist if the market share exceeds 35 per cent, unless the undertaking proves that it faces significant competition from its rivals; for other cases where dominance can exist, see question 25. For this reason, transactions where either party has close to or over a 35 per cent market share can be problematic, while market shares of 15 to 35 per cent are likely to draw additional attention. Still, under the Horizontal Mergers Guidelines recently adopted by the AMC, high market shares provide only first indicators of the competition concerns, and when assessing the merger, the following aspects should also be taken into account:

- the Herfindahl-Hirschman Index levels;
- the likelihood of anticompetitive effects in the relevant markets;
- the likelihood that buyer power, market entry or efficiencies would act as a countervailing factor to potential anticompetitive effects; and
- conditions for a failing firm defence.

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

Information on the products in the pipeline is not strictly required. However, if the notifying parties seek to be as compliant as possible and include respective discussions in the notification, the AMC would likely pick up on this issue and request that the parties evaluate any possible effects.

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

For domestic mergers notified to the AMC, the authority may request parties not to exceed a certain level of prices for selected medicines (usually socially sensitive; eg, anti-flu drugs, over-the-counter medicines), not to limit their production without sensible reasons; it would also usually impose reporting obligations to monitor overall compliance and see how the situation develops with respect to problematic products with a view to intervene where necessary. Structural remedies are also possible. In foreign-to-foreign mergers, the AMC often imposes reporting obligations and requests that the undertakings concerned refrain from unjustified price increases; these requirements only concern products present on the Ukrainian market.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

It is unclear whether acquisitions of licences constitute mergers. If, in addition to the licences, there are other assets being acquired, the merger requirement is likely to apply (assuming that the reporting thresholds are hit). If only the licence is being acquired, clearance may still be required in some situations. Additionally, if the transfer of the licence includes restrictions or may otherwise have potential effects on competition, separate antitrust clearance may be required. See question 17.

Anticompetitive agreements

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

An agreement or practice can be considered anticompetitive if it has the prevention, elimination or restriction of competition as its object or effect. Below is a non-exhaustive list of practices that are hard-core restrictions:

- fixing prices or other purchase or sale conditions;
- limiting production, markets, technological development or investment, as well as assuming control of them;
- dividing markets or sources of supply according to territory, type of goods, sale or purchase volumes, or classes of sellers, buyers or consumers;
- distorting the results of trading, auctions, competitions or tenders;
- ousting other companies from the market or limiting their market access;
- applying different conditions to identical agreements to put a specific company at a disadvantage;
- executing agreements that are conditional on the contracting party's acceptance of additional obligations unrelated to the subject of the agreement;
- substantially limiting the competitiveness of other companies without justifiable reasons; and
- parallel behaviour (actions or omissions) that resulted or may result in the prevention, elimination or restriction of competition is also considered a violation, unless there are objective reasons for that.

There are also general exemptions and block exemptions. Prohibition of anticompetitive practices will not apply:

- where the aggregate market share of the parties (including their respective corporate groups) in any of the product markets concerned is less than 5 per cent (except for hard-core restrictions; see below); or
- to vertical or conglomerate arrangements where the parties' combined market share is below 20 per cent, and to horizontal and mixed arrangements where the parties' combined market share is below 15 per cent. However, market share-based exemption cannot apply if (cumulative conditions):
  - the aggregate worldwide turnover or assets value of the parties (including their respective groups) exceeded €12 million in the preceding financial year;
  - the aggregate worldwide turnover or assets value of at least two undertakings that belongs to the parties' groups separately exceeded €1 million in the preceding financial year; or
  - the aggregate turnover or assets value in Ukraine of at least one undertaking that belongs to either party's group exceeded €1 million in the preceding financial year.

However, it appears that, in practice, the value of assets or turnover test does not serve as an appropriate benchmark for the AMC to assess potential competition concerns, especially as regards vertical restraints, where effects on competition primarily depend on the market position of the parties (for example, their market shares).

If the parties are at least potential competitors, the general exemptions do not apply to horizontal or mixed hard-core restrictions, including:

- price fixing;
- territorial, customer or supplier and other market sharing;
- restrictions on (including imposing an obligation to refrain from) production or distribution of products; and
- distortion of the results of trading, auctions, competitions or tenders.

The exemption under the R&D Regulation applies when the combined market share of the parties on the relevant market does not exceed 25 per cent and the parties meet a set of other criteria (for example, equal access to the results of the R&D activity).

When assessing their practices, undertakings may obtain advice from the AMC regarding their compliance with competition legislation. It is also possible to seek authorisation (individual exemption) of certain potentially anticompetitive concerted practices if:

Update and trends

Horizontal Mergers Guidelines adopted by the AMC in December 2016

The key developments introduced by the Guidelines that are likely to have the most appreciable impact on mergers are:

- wider types of evidence and considerations that carry weight for the AMC when it is granting clearance (eg, market entries and expansion, HHI levels, cross-price elasticities of the products involved or diversion ratios);
- an adjustment of the evidentiary weight of market shares;
- the introduction of unilateral and coordinated theories of harm (the AMC emphasises that the overview of theories of harm in the Horizontal Mergers Guidelines cannot be exhaustive and factors other than those discussed in the document may also be relevant);
- clarification on the evidence supporting powerful buyers, market entry and efficiencies as countervailing factors influencing the AMC's analysis (for example, the evidence of entry by other likely competitors can be significant evidence influencing the AMC); and
- the introduction of the failing firm defence.

Completion of two major investigations in the pharmaceutical sector

The investigations concerned suspected anticompetitive concerted practices between two pharmaceutical manufacturers and several Ukrainian distributors, and resulted in fines in the overall amount of approximately €174,000. Among the actions viewed by the AMC as anticompetitive concerted practices are:

- non-transparent retroactive rebate schemes between the manufacturers and distributors, allowing the latter to overcharge pharmaceuticals in tender proceedings; and
- reporting obligations of the distributors before the manufacturers.

Several more investigations in the sector are still pending and are expected to be completed in 2017.

- the parties can prove that these practices encourage manufacturing, technological or economic development, or other efficiencies; and
- the practices do not lead to a substantial restriction of competition.

18 To what extent are technology licensing agreements considered anticompetitive?

Such agreements would not normally be considered anticompetitive, as far as they contain standard permissible restrictions, such as duration or territory of use of the licence, types of activities and sphere of use, as well as minimal volume of production.

However, minimal volume of production may raise the AMC's concern if it limits the competitiveness of the undertaking, or, for example, if there exists an unreasonably high quota that may oust other companies from the market or limit their market access.

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

This may be the case if the cooperation removes or lessens competition between the parties having appreciable market presence (eg, securing marketing channels or control over sales). Achieved advantages, such as extra discounts or exclusivity, may also be problematic.

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

Any agreement or behaviour that satisfies criteria outlined in question 17. The confidentiality provisions between the parties may reduce the likelihood of the agreements coming to the AMC's attention; still, they will not resolve the underlying issue of whether there is any anticompetitive conduct.

It is also worth mentioning that in the AMC's opinion confidentiality provisions may be anticompetitive. The AMC has been encouraging companies to make their conditions transparent, available to third parties and end customers, justifiable and non-discriminatory. It is assumed that by having access to such conditions an interested party can better plan its activity and benefit from them generally.

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

Exclusivity is one of the most problematic issues. Other common problems include retroactive discounts, individualised sale terms and conditions (eg, special discounts), unreasonable additional services (eg, marketing) coupled with unjustified level of compensation for them.

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

There are no relevant cases or rules; general restrictions apply. The settlement will qualify as an agreement. See question 17.

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

Exchange of information is not expressly regulated by competition laws and general rules on concerted practices apply. In the investigations conducted by the AMC so far, the information exchange has not raised substantial concerns. However, the issue may attract more attention as the AMC's enforcement practice evolves.

Anticompetitive unilateral conduct

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

Any conduct (actions or failure or refraining to take certain actions) of a dominant (or monopolist) undertaking that resulted or may result in the prevention, elimination or restriction of competition or harm to the interests of other undertakings or consumers may be regarded as abuse of dominant (or monopolist) position on the market. In order to be found abusive, such conduct should not be possible in a highly competitive environment.

When investigating a potentially abusive conduct, the AMC must first assess whether the undertakings concerned are dominant on the relevant market. For that purpose the AMC will primarily define the relevant product and geographical market (see question 11 for the market definition) and calculate the market share of the undertakings concerned on that market.

As a general rule, the following unilateral conduct is considered abuse of a dominant position:

- setting of prices or other conditions of purchase or sale of products that could not have been set in a highly competitive environment;
- applying dissimilar prices or other conditions to equivalent transactions without valid justification;
- making the conclusion of contracts subject to acceptance of supplementary obligations that, by their nature, or according to commercial usage, have no connection with the subject of such contracts;
- limiting of production, markets or technical development that harmed or may harm other undertakings or customers;
- refusing, in part or in full, to purchase or sell goods in the absence of alternative sources or distribution channels;
- significant limiting of competitiveness of other undertakings without valid justification; and
- creating barriers for market entry or exit.

The above list is indicative; it only outlines the AMC's approach to assessment of unilateral conduct in the context of dominance. Any other type of harmful restrictive behaviour of an undertaking with market power may be found to be abusive.

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

An undertaking will be presumed to hold a dominant position if its market share on the relevant market exceeds 35 per cent, unless such undertaking proves that it faces significant competition from its rivals.

Collective dominance is presumed if the three largest market players jointly have more than 50 per cent of the market, or the five largest market players jointly have more than 70 per cent of the market.

In rare cases, a company with a smaller market share may be found dominant if such undertaking does not face significant competition from other market players, for instance, because of competitors' considerably smaller market shares.

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

There are no relevant rules or cases. By analogy to other cases, a company may be found dominant, but there are many other factors that need to be analysed. Essentially, this may be the case if the patent is in use and the product is present on the market and holds a dominant position.

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

A patent application does not provide exclusive proprietary rights to the applicant. Limited right to compensation arises when the patent application is published, however, such compensation may only be sought after the patent has been granted. At the same time, Ukrainian patent laws are clear that the patent owner has the exclusive right to prohibit the unauthorised use of an invention or utility model by others, and is entitled to apply to court in order to enforce his or her patent rights.

Therefore, an application for, or the actual grant of a patent alone, as well as bona fide application for enforcement, cannot be viewed as an antitrust violation. However, applying for the enforcement of a patent may be considered by the AMC as unfair competition practices where the purpose of the enforcement is to prevent other companies from the legitimate business operations. For example, the so-called 'patent trolling' may expose the patent owner to liability for an antitrust violation.

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

General restrictions for unilateral conduct apply; see question 24.

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

No special restrictions, general rules or prohibitions apply; see questions 17 and 24.

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

There are no specific rules, but various efficiencies are more likely to be accepted by the AMC as justification than in other industries.

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

Not applicable.

Asters

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

The Human Medicines Regulations 2012 (SI 2012/1916) (HMR), which came into force on 14 August 2012, replaced nearly all of the UK's existing medicines regulation, consolidating the rules on drug manufacturing, importation, distribution and packaging. It also provided for the implementation of the European Union legislation on pharmacovigilance. The HMR creates one set of regulations that are in line with EU law, and its publication is the result of a wide-ranging review and consultation by the UK medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA is an executive agency, sponsored by the Department of Health.

The HMR is divided into several different parts. Part 3 of the HMR contains the rules for manufacturing, importing and wholesale dealing. It requires that these activities be the subject of a licence and establishes what the licensing authority must consider when assessing an application for a licence. It also provides rules around the suspension, revocation and variation of licences. Part 4 contains the requirement that medicinal products be the subject of a marketing authorisation, while Part 5 contains detailed requirements regarding marketing authorisations, setting out the material that needs to accompany applications for authorisations and making specific provision for generic medicinal products, biological medicinal products, products with well-established medicinal use and new combinations of active substances. Part 5 also imposes certain obligations on authorisation holders, such as a requirement to take into account scientific and technical progress, and contains rules relating to revocation, variation, withdrawals and suspensions.

The marketing of pharmaceuticals is also self-regulated by industry codes, including the Association of the British Pharmaceutical Industry (ABPI) Code for prescription-only medicines and the Proprietary Association of Great Britain for over-the-counter (OTC) medicines. Compliance with these codes is not compulsory, although in practice manufacturers generally adhere to them.

Prices of most branded medicines are controlled by the Pharmaceutical Price Regulation Scheme (PPRS). The PPRS is a voluntary scheme between the Department of Health acting on behalf of the UK government and Northern Ireland, which includes the Health Departments of England, Wales, Scotland and Northern Ireland, and the ABPI. The PPRS applies to all branded, licensed health service medicines supplied by members for health service use within the UK. It does not cover sales of products on private prescription or other use outside the health service in the UK or branded products available without prescription (OTC medicines), except when these are prescribed. Nor does it cover the pricing of generic (ie, unbranded) products, as the view is that – following generic entry – competition between generic products will keep prices low without the need for regulation. The PPRS caps the overall profits that companies can make from NHS sales, and it is typically renegotiated every five years. The current scheme was launched in January 2014 and runs until 31 December 2018. The 2014 scheme differs from previous schemes in that the NHS has a fixed spending amount on branded medicines each year.

The relevant statutory powers covering pharmaceutical pricing are contained within the National Health Service Act 2006 (the 2006 Act) and subordinate legislation. The Secretary of State for Health's primary powers to limit the prices of, or the profits accruing from, health service medicines are found in sections 261–266 of the 2006 Act. Regulations setting out the requirements for the statutory scheme are set out in the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008, and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc) Regulations 2007. These Regulations were amended by the Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013. The 2013 Regulations came into force on 1 January 2014. The amendments brought the statutory scheme into better alignment with the PPRS.

The MHRA is the body entrusted with enforcing the HMR.

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

Part 3 of the HMR sets out in further detail conditions for licensing of wholesale dealers, and restrictions on their activities, to ensure, among other things, compliance with European Commission (Commission) guidelines on good distribution practices (relating to quality assurance, facilities assurance, proper authorisations, etc).

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

Regulation plays a role in framing the competitive landscape, although the interaction of regulation and competition law is complex and multifaceted. Companies must comply with the requirements of the HMR and are constrained in terms of pricing in relation to medicines sold to the NHS by the PPRS and the statutory pricing scheme. However, restrictions within the regulatory framework may also distort competition and companies may try to take advantage of such features to their benefit.

Competition legislation and regulation

4 Which legislation sets out competition law?

The UK competition rules are contained generally within two statutes: the Competition Act 1998 (CA 1998) and the Enterprise Act 2002 (EA 2002). The CA 1998 contains two main prohibitions.

Chapter I (section 2, CA 1998) prohibits any agreement or concerted practice that has the object or effect of preventing, restricting or distorting competition, unless an exemption from the prohibition applies. Where the agreement or concerted practice also affects trade between member states of the EU, it may also be prohibited by article 101 of the Treaty on the Functioning of the European Union (TFEU). A restriction that infringes the prohibition is void and unenforceable.

Chapter II (section 18, CA 1998) prohibits the abuse of a dominant market position that has or is capable of having an effect on trade within the UK. Such an abuse may also breach article 102 of the TFEU to the extent that it affects trade between EU member states.

The EA 2002 contains a criminal cartel offence for individuals and sets out the UK merger control rules and the market studies and investigations regime.

Both the CA 1998 and the EA 2002 were amended by the Enterprise and Regulatory Reform Act 2013 (ERRA). The ERRA provided for the establishment of the Competition and Markets Authority (CMA), which, on 1 April 2014, took over the competition and certain consumer functions and powers from the two UK competition authorities in charge prior to this date, the Office of Fair Trading (OFT) and the Competition Commission. The CMA has been given stronger powers of investigation where it suspects an infringement of the prohibitions. This includes a new power to require individuals connected to a business under investigation (eg, directors or employees) to answer questions (section 26A, CA 1998).

Under the EA 2002, an individual who is directly involved in the most serious types of anticompetitive agreement between businesses can face criminal prosecution (section 188, CA 1998). The ERRA removed the requirement that an accused individual must have acted 'dishonestly', meaning that mere participation in the anticompetitive practices is sufficient for committing the offence. However, to provide some protection against the tougher offence being applied too strictly, there are now a number of exclusions from, and defences against, the offence (sections 188A and 188B, CA 1998). The CMA has pursued a number of criminal prosecutions since the ERRA came into force under the old 'dishonesty' test where the conduct in question pre-dated April 2014. Although, as far as has been disclosed, none of these prosecutions have been in the pharmaceutical sector.

The CMA has wide powers under the EA 2002 to investigate markets where there are concerns that competition may not be operating effectively, including by reason of the relevant structure of the market (Part 4, EA 2002).

The ERRA13 preserved the UK's voluntary merger regime in which – unusually, in the global context – mergers can be completed without making a notification to, or receiving clearance from, the UK competition authorities. However, parties that complete mergers prior to clearance risk imposition of 'hold separate' orders, which require them to maintain strict separation of the merged businesses, and the possibility of an order to divest the acquired business in the event of a subsequent review finding irresolvable competition problems. The CMA has jurisdiction to review any transaction where the target has a UK turnover in excess of £70 million or the transaction leads to the creation or strengthening of a 25 per cent share of supply for sale of any goods or services in the UK (or part of the UK). This test has been interpreted broadly, and the de minimis exemption for smaller transactions is very limited, meaning careful review is necessary in any acquisitions involving overlapping activities.

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

The CMA has jurisdiction to investigate and decide pharmaceutical mergers that satisfy the relevant jurisdictional thresholds (section 23, EA 2002). A merger giving rise to a 'concentration' with an EU dimension may instead be subject directly to EU Merger Regulation (Regulation 139/2004/EC), if the relevant EU turnover thresholds are met, in which case the relevant authority is the European Commission.

The CMA is also responsible for investigating anticompetitive conduct or arrangements within the UK (see question 4). Where the anticompetitive conduct or arrangement affects trade between member states, the European Commission is the authority that investigates the conduct or arrangement.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

The CMA can impose fines on a company of up to 10 per cent of the company's worldwide turnover for the previous financial year. The CMA's predecessor, the OFT, imposed fines on pharmaceutical companies in three cases, each involving abuse of dominance contrary to the Chapter II prohibition, and article 102 of the TFEU, of:

- £3.21 million on Napp Pharmaceuticals Holdings Limited in 2001 (reduced to £2.2 million on appeal) for abusive conduct concerning the supply of sustained relief morphine (SRM) tablets and capsules in the UK (including supplying hospitals at excessively low discount levels and targeting discounts so that competitors' SRM products had difficulty competing);
- £6.8 million on Genzyme Limited in 2003 (reduced to £3 million on appeal) for abusive conduct (tying and margin squeeze abuses) in relation to the supply of drugs for the treatment of Gaucher disease (an enzyme deficiency disorder); and
- £10.175 million on Reckitt Benckiser in 2011 for withdrawing and de-listing its product 'Gaviscon Original Liquid' from the NHS prescription channel after the product's patent had expired but before the publication of the generic name for the product. This meant that when doctors searched for 'Gaviscon' prescription packs, they only identified the newer product 'Gaviscon Advance Liquid', which was patent protected until 2016. This practice is known as 'product hopping' or 'product switching' and its purpose is to shift demand to the new patent protected product for which there are no generic alternatives, thereby limiting competition from other suppliers. The fine would have been £12 million but was reduced following the company's decision to cooperate and admit the infringement.

The CMA has recently imposed the following fines on pharmaceutical companies:

- £44.9 million on GlaxoSmithKline and other pharmaceutical companies for anticompetitive conduct and agreements in relation to the supply of the antidepressant drug paroxetine. The CMA's decision relates to patent settlement agreements between GlaxoSmithKline and a number of generic companies following allegations that the generic products would infringe GlaxoSmithKline's patents. The settlement terms involved 'value transfers' from GlaxoSmithKline to the generic companies, which, according to the CMA, were aimed at delaying the entry of generic paroxetine into the UK market. This is the first UK decision to consider the application of competition law to patent settlement agreements. The decision against GSK also involved an allegation of abuse of dominance. The parties have appealed the CMA's decision to the CAT with a hearing listed for 27 February 2017.
- £88.9 million on Pfizer and its distributor Flynn Pharma for abusing a dominant position by charging excessive and unfair prices for phenytoin sodium capsules used in the treatment of epilepsy. Both parties have appealed the CMA's decision to the CAT. In the meantime, the parties must reduce their prices although no indication has been provided by the CMA as to what their prices should be.

Over the past year, the CMA has become increasingly active in the pharmaceutical sector. As well as the above fines, in December 2016, the CMA adopted a statement of objections against Actavis UK for infringing competition law by charging excessive prices to the NHS for hydrocortisone tablets for the treatment of patients whose adrenal glands do not produce sufficient amounts of natural steroid hormones.

The CMA's increased scrutiny of the pharmaceutical sector follows the European Commission's pharmaceutical sector inquiry in 2008 and the Commission's high-profile cases that subsequently followed:

- *Johnson & Johnson and Novartis*;
- *Servier*;
- *Lundbeck*; and
- *Cephalon and Teva*.

While the CMA's *GSK* case follows the Commission's decisions in *Servier* and *Lundbeck* challenging so-called 'pay-for-delay' settlement agreements between originators and generics, the new focus on so-called excessive pricing by companies whose products are outside of the PPRS is a new development that creates significant new risks for companies in the pharmaceutical sector.

The CMA operates a leniency programme that offers successful applicants immunity or a reduction in fines to companies that blow the whistle on cartel offences. A company may also gain a reduction in any financial penalty imposed in return for cooperating and admitting its involvement in anticompetitive conduct pursuant to the CMA's settlement or 'early resolution' procedure.

The CMA can accept binding commitments from companies under investigation (section 31, CA 1998), enabling it to resolve its competition concerns quickly and avoid a full investigation. This is akin to a settlement agreement. Other remedies include the power to order companies that have infringed the rules to cease or modify their activities (sections 32 and 33, CA 1998).

The CMA may impose interim measures to terminate the relevant commercial practices pending the final outcome of an investigation where continuance of the conduct would cause 'significant damage' to another business (section 35, CA 1998).

An individual who is found guilty of the cartel offence will be liable to a criminal sentence of up to five years' imprisonment instead of, or in addition to, an unlimited fine (section 190, EA 2002). Individuals can seek protection from prosecution by whistle-blowing to the CMA, provided they admit the offence, were not the 'ringleader' or instigator of the cartel, supply evidence of the existence of a cartel and cooperate fully with the CMA.

Company directors that are found to have infringed the Chapter I or II prohibition (or articles 101 or 102 TFEU) can face disqualification for a maximum period of 15 years. The CMA, having reached a final infringement decision, will seek an order stating that the director's actions render him or her unfit to be a director, for example, on the grounds of contributing to the company's anticompetitive conduct. The CMA has indicated an intention to increase the number of director disqualification orders in future investigations.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

The UK courts have long recognised that private parties enjoy a right to seek damages if they have suffered loss as a result of an infringement of competition law. Typically such damages claims will follow on from an infringement finding by the CMA, Commission or another regulator (with the English courts being a preferred EU venue for such actions). Damages actions in the pharmaceutical sector include claims by:

- the Department of Health (among others) against Ranbaxy, Goldshield, Norton Healthcare Limited and Generics UK for alleged anticompetitive cartel conduct in connection with the supply to the NHS of generic drugs between 1996 and 2000;
- Healthcare at Home (2006) against Genzyme, based on the OFT's 2003 decision – the claim was withdrawn in early 2007 following a settlement between the parties, but not before the UK Competition Appeals Tribunal (CAT) granted Healthcare At Home an interim payment of £2 million;
- the UK health authorities (namely the English, Scottish, Welsh and Northern Irish health authorities) against Reckitt Benckiser following the OFT's decision against Reckitt in 2011 for abuse of a dominant position;
- Teva UK Limited and Norton Healthcare Limited, generic competitors of Reckitt Benckiser (commenced in the CAT but later transferred to the High Court to join the claims launched by the UK health authorities against Reckitt) also following the OFT's decision in 2011; and
- the UK health authorities in 2011 and 2012 against four companies in the Servier group. These followed an announcement by the Commission on 8 July 2009 that it had opened an investigation into suspected breaches of articles 101 and 102 of the TFEU by Les Laboratoires Servier (Servier) and a number of generic pharmaceutical companies, which later led to it imposing fines on Servier and five generic companies totalling €427.7 million for practices that delayed generic entry of the cardiovascular drug perindopril. The parties have appealed the Commission's Decision to the EU General Court, and it can be expected that the General Court's decision will have implications on the case pleaded by the claimants in the national proceedings.

Certain specified consumer bodies can also bring claims on behalf of a group of representative claimants and any damages awarded as a result of the claim will be apportioned between the claimants. This is less likely in pharmaceutical cases because it is the Department of Health and the various UK health authorities that are likely to bring actions.

The Consumer Rights Act, which came into force in October 2015, has introduced a range of reforms to the procedure for bringing private actions in competition law. For example, the Consumer Rights Act broadened the CAT's jurisdiction so that it can now hear 'standalone' claims (that is, claims that do not rely on infringement decisions of the CMA or European Commission). Claimants can also seek interim measures to restrain alleged anticompetitive behaviour. In 2007, a group of pharmaceutical wholesalers applied to the High Court for an interim injunction preventing Pfizer from ceasing to supply them with pharmaceuticals following a change in Pfizer's distribution arrangements. Prior to applying to the High Court, the wholesalers had sought but were denied interim measures from the OFT (a process that lasted approximately four months). The High Court refused the wholesalers' application for an injunction on various grounds, including that the application had been delayed.

Where a damages claim follows on from an infringement finding by a competition authority, the availability of evidence to the claimants will be an important consideration. The EU Damages Directive contains provisions designed to resolve any uncertainty about what information from the competition authority's investigation falls to be disclosed in any subsequent litigation. This is intended to facilitate damages claims by victims of anticompetitive conduct. Three categories of evidence are addressed: leniency statements by whistle-blowers, which are protected from disclosure; information prepared specifically for the proceedings of the competition authority (eg, responses to statements of objection and information requests), which are only disclosable once the authority has closed its investigation; and all other types of evidence (eg, internal factual materials) that fall to be disclosed.

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

Market studies form a critical element of the CMA's toolkit. On concluding a market study, the CMA can (among other things) decide the market is functioning well, take enforcement action or make recommendations to the government to change regulations or public policy. Where the CMA decides that a more detailed examination of the relevant market is required, it will refer the market for investigation (section 131, EA 2002). Unlike EU sector inquiries, CMA market investigations can lead directly to the imposition of significant remedies without any breach of competition law needing to be established. The critical issue is whether there is an adverse effect on competition in the market or markets for the goods or services referred. If so, the CMA must decide what remedial action, if any, is appropriate.

The OFT conducted a couple of market studies looking into conduct in the pharmaceutical sector in 2007. These were a study into the PPRS, which concluded that the introduction of profit and price controls were inappropriate and recommended their replacement with patient-focused, value-based pricing; and a study into the distribution of medicines, which concluded that 'direct-to-pharmacy' arrangements were unlikely to give rise to competition concerns. However, it did conclude that direct-to-pharmacy arrangements could lead to longer delivery and waiting times and that the future widespread use of exclusive agreements might lead to long-term competition concerns, and that it would monitor the situation. The OFT's findings were taken into account when the PPRS was renegotiated. As at the date of writing there has been no further action by the CMA on direct-to-pharmacy schemes.

The CMA has not yet examined pharmaceutical markets but recently published a final report into privately funded healthcare services (October 2014), finding that there was a lack of publicly available information on healthcare performance and fees and that this adversely affected competition in the market. The CMA therefore required private healthcare operators and consultants to provide up-to-date information on their performance and fees to an independent information organisation, which will produce a public website and an industry portal of useful healthcare information. The CMA's requirement on publication of consultant fees is currently being challenged in the CAT.

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

Non-governmental groups may submit complaints to the CMA. In addition, certain non-governmental consumer bodies, including Citizens Advice and Which?, may initiate a 'super complaint' where they consider that there are market features that may be harming consumers in the UK to a significant extent (section 11, EA 2002). This imposes an obligation on the CMA to take action to investigate the complaint as a matter of urgency.

Review of mergers

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

The UK merger rules are not, in general, tailored towards particular industries and the CMA will approach each case on its merits. Therefore, while there are no pharmaceutical industry-specific competition rules, particular features of the industry may be taken into account in a particular case – and the CMA will refer to precedent from the Commission in relation to issues such as market definition within the pharmaceutical sector, which has been well-developed in previous cases (see question 11). The critical issue is whether a transaction results in a substantial lessening of competition (SLC), which will be determined by reference to elimination of close competition in particular.

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

The CMA typically follows the Commission's approach to definition of the relevant market for pharmaceutical products – that is, subdividing pharmaceuticals into therapeutic classes by reference to the anatomical therapeutic chemical (ATC) classification system, developed and maintained by the European Pharmaceutical Marketing Research Association. The third ATC level (ATC3), specifying the therapeutic indication, has generally been used as a starting point for defining product markets (although in recent cases involving generics, the Commission has tended to identify competition issues at the ATC4 or molecule level, similar to its approach in articles 101 and 102 investigations). Geographic markets are typically held to be national. Whereas a narrower (ATC4 or ATC5) product market can make it easier to establish a dominant position in article 102 investigations, in merger reviews, use of ATC3 will make it more likely that merging parties will be considered competitors in the first instance, even if their products differ under the lower level ATC classifications.

The CMA utilised this approach in its assessment of the completed acquisition by ProStrakan Group plc of Archimedes Pharma Limited (CMA decision, 1 December 2014). The parties overlapped at ATC3 level in the supply of fast-acting fentanyl products in the UK that are licensed for the management of breakthrough cancer pain. The CMA held that Archimedes did not materially constrain ProStrakan in the supply of fast-acting fentanyl products before the merger, primarily because of its relatively small share of supply and the limited extent to which Archimedes' product, PecFent, is considered a close substitute to ProStrakan's (Abstral). (The brands have different modes of administration – the former being a nasal spray and the latter a sublingual tablet.) The CMA also found that there were other credible suppliers of fast-acting fentanyl products, which would continue to constrain the merged entity. The appropriate geographic frame of reference was the UK.

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

The UK regime provides for the possibility of efficiencies off-setting competitive harm caused by a merger, and thus preventing an SLC arising. It also provides for consideration of 'relevant customer benefits', which could in theory include local R&D developments, which might be seen to outweigh an SLC where one has been identified.

In terms of demonstrating efficiencies, the CMA requires that these be timely, likely, sufficient and merger-specific. The standard of proof is high, notably in phase one reviews where the evidence must be 'compelling'.

However, while efficiencies arguments have been put forward in various cases, and appear to have weighed into the overall assessment in certain cases, there have not to date been any clear-cut cases where a transaction that otherwise led to an SLC was found not to raise concerns on the basis of efficiencies or relevant customer benefits. Companies considering transactions in the pharmaceutical sector would therefore be well advised not to rely wholly on efficiencies or other customer benefits, such as development of R&D, if the transaction will otherwise be likely to lead to an SLC.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

Horizontal mergers can give rise to concerns where they lead to a substantial lessening of competition because of:

- 'unilateral' effects: if the merger removes an important competitor from the market, allowing the merged business to profitably raise prices; or
- 'coordinated' effects: if the merger enables or encourages coordination (ie, when companies operating in the same market recognise that they can reach a more profitable outcome if they limit the extent to which they compete against each other).

Vertical mergers, although normally considered less harmful, can give rise to issues where they restrict downstream competitors' access to a key input or restrict upstream competitors from a key 'route to market'. As above, where merging parties have products within the same ATC3 classification, this will lead to prima facie concerns. The CMA has not had to address as many pharmaceutical mergers as the Commission, but the market share filters applied by the Commission will also influence the CMA's approach. Under these filters, horizontal market overlaps are not treated as problematic where the combined share is either over 35 per cent but with an increment in share of below 1 per cent, or below 35 per cent. Note that vertical overlaps between a manufacturer of the active pharmaceutical ingredient (API) and the finished product may also raise concerns (under the EU thresholds, where an API share over 30 per cent is combined with a finished product share over 5 per cent, or where a finished product share over 25 per cent is combined with an API share over 5 per cent).

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

The issue of potential competition is particularly relevant in the pharmaceutical sector: to what extent should pipeline products in development be considered competitors to products already in the market, and to what extent are generic alternatives competitive alternatives to the originator's product? Looking at the EU merger guidelines, the starting point is whether potential competition already exerts a significant constraint on the active party (or is sufficiently likely to do so), and then whether there are sufficient other potential competitors to offset such possible harm. The Commission has previously considered cases involving pipeline products and mergers where both parties have had pipeline products, and the Commission was required to consider elimination of competition between two products, neither of which were yet available in the market (eg, *Merck/Schering Plough* in 2009). The Commission has considered the extent to which generic suppliers were close competitors (eg, *Teva/Cephalon* in 2011).

The UK authorities have previously considered 'pipeline products' when investigating the potential effects of a merger. Typically, this has involved assessment of the merging parties' businesses at each phase of clinical trials and over all clinical trials. The OFT previously suggested that the markets for pipeline products could be defined on the basis of the underlying R&D activity, which is usually global.

In 2009, when assessing a joint venture between GlaxoSmithKline and Pfizer, the OFT considered the markets for HIV drugs that had already been marketed and drugs that were in the pipeline. A key issue was whether the joint venture would lead to the termination, or slowing down of, the development of one of the parties' overlapping products. The OFT found that any effect on competition would be offset by competition from similar products at a more advanced stage of development or products already on the market. The OFT decided the geographic market was at least EEA-wide, noting that the Commission has, in previous cases, defined the market for future products as at least EEA-wide or possibly worldwide in scope.

In discussing potential competition in the pharmaceutical sector, it is worth referring to the Technology Transfer Block Exemption (TTBE), which applies to agreements between parties rather than mergers, though an analogy can be drawn. The old position under the TTBE was that the existence of a 'blocking position' (ie, IP rights) meant that parties were treated as non-competitors. However, the new position is that parties may be treated as potential competitors, regardless of any IP rights, if the parties have made 'advanced plans to enter

the market'. The General Court's decision in *Lundbeck* (which entirely upheld the Commission's decision) is evidence that the authorities are more willing to define generic companies as potential competitors despite the existence of IP rights in the context of investigations, and a similar approach may be expected in mergers to the extent this allows authorities to address possible overlaps that could raise concerns.

The General Court's evaluation of 'potential competition' in *Lundbeck* is worth briefly reflecting on. The General Court found the fact that the generic companies had possibilities for entering the market, including by launching 'at risk' of infringing Lundbeck's patent, was sufficient for them to be regarded as potential competitors. In reaching the conclusion that launching 'at risk' was an expression of potential competition, the General Court relied on three factors:

(i) Lundbeck's compound patent had expired (but Lundbeck's patents covering processes for the manufacture and crystallisation of citalopram remained in place);
(ii) there were other processes available to produce citalopram that were non-infringing; and
(iii) the generic companies had taken steps and made investments to enter the market in competition with Lundbeck, including obtaining the API, applying for a marketing authorisation, and actively seeking customers for their generic products.

This analysis necessarily assumes that Lundbeck's patent would have been invalidated, despite the General Court acknowledging that patents should be presumed valid once they have been granted. The General Court also failed to give weight to the arguments of the generic companies that there were commercial and regulatory barriers to entry, noting instead that the fact that Lundbeck had entered into settlement agreements with the generic companies indicated that it perceived those undertakings as potential competitors.

Finally, the General Court indicated that competition could occur several years before the expiry of the compound patent when generic producers who want to launch a product begin developments leading to a product that obtains a marketing authorisation. Effectively, this means that a generic that is up to eight years from market entry could be considered a potential competitor.

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

At the outcome of a Phase I merger investigation, the CMA may accept undertakings 'in lieu' of a reference to a Phase II investigation. Furthermore, at the outcome of the Phase II investigation, the CMA may decide to clear a particular merger subject to the implementation of remedies by the parties in question. The CMA has not yet imposed remedies in a pharmaceutical merger, although the OFT accepted behavioural remedies in *IVAX/3M* (decision of 20 October 2003). The parties overlapped in the supply of salbutamol and beclomethane dipropionate-based hydrofluoroalkane inhalers used to treat asthma. IVAX agreed not to increase the prices of its inhalers unless a new inhaler, not produced by IVAX or its group, entered the UK market.

The CMA's general preference is for structural remedies (ie, divestments) rather than behavioural remedies, as they are more clear-cut and do not require ongoing monitoring. This is particularly the case in Phase I. That said, brand licensing arrangements have been accepted as a remedy in the recent acquisition by Reckitt of the K-Y brand from Johnson & Johnson at the end of Phase II (and a licensing remedy was also considered as an option at Phase I). Where parties prefer to offer a licence, and this is an effective remedy, the CMA may consider it, but will only require an assignment of intellectual property rights in exceptional circumstances. Section 86(2) EA 2002 prevents the imposition of remedies interfering with conditions in patent licences and licences of registered designs.

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

As a general rule, the transfer of assets alone will not give rise to the existence of a merger. The merger regime in the UK applies where two or more enterprises 'cease to be distinct'. Therefore, intellectual property rights will not generally constitute an 'enterprise' in their own right for the purposes of Part 3 of the EA 2002. However, the sale of an asset together with the benefit of contracts (with customers, suppliers, etc) may be caught by the rules, notably where it is possible to identify turnover that will transfer with the intellectual property rights.

Anticompetitive agreements

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

The Chapter I prohibition comprises four parts, which must each be satisfied for the prohibition to be infringed. There must be:

- an agreement, decision or concerted practice;
- between undertakings;
- that may affect trade within the UK; and
- that has as its object or effect, the prevention, restriction or distortion of competition within the UK.

The prohibition covers a range of behaviours including price fixing, bid rigging, resale price maintenance and exchanging competitively sensitive information.

An agreement caught by the prohibition may be eligible for exemption pursuant to section 9, CA 1998, provided it improves production or distribution or promotes technical or economic progress, while allowing consumers a fair share of the resulting benefit, and does not impose unnecessary restrictions on competition or allow the parties to the agreement the opportunity to eliminate competition.

18 To what extent are technology licensing agreements considered anticompetitive?

There are no UK-specific competition laws covering technology licensing agreements. On 1 May 2014, the Technology Transfer Block Exemption Regulation (TTBER) (Commission Regulation (EU) No. 316/2014) entered into force. The TTBER defines certain categories of technology transfer agreement that do not raise competition concerns. It creates a 'safe harbour' for licensing agreements concluded between companies that have limited market power and that respect certain conditions. Such agreements are deemed not to have an anticompetitive effect or (to the extent they have any) the positive effects are considered to outweigh the negative ones.

Certain clauses fall outside the block exemption's safe harbour (and must be assessed on a case-by-case basis), including clauses:

- requiring the licensee to exclusively license back to the licensor and not use its improvements to the technology;
- preventing a licensee from challenging the validity of a technology; and
- providing for termination of the agreement if a licensee challenges the validity of the technology's intellectual property rights (although terminate-on-challenge clauses in exclusive licences do benefit from the safe harbour unless the market share thresholds are met).

The TTBER applies to patent settlement agreements where a licence is granted. The new Guidelines emphasise that any patent settlement agreement involving a 'value transfer' by the IP owner to the potential infringer in return for restrictions on the latter's entry onto the market will be closely scrutinised. The Guidelines state that if the parties 'are actual or potential competitors and there was a significant value transfer from the licensor to the licensee, the Commission will be particularly attentive to the risk of market allocation/market sharing'. The Guidelines refer to such agreements as 'pay-for-restriction' or 'pay-for-delay' settlements.

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

Under co-promotion agreements, a company that has developed a product will agree with another company (often a competitor) to promote the product under a common brand and marketing strategy. Co-marketing, in comparison, involves two companies (often competitors), simultaneously marketing and selling the same product under different brand names. In assessing such agreements, the CMA will have regard to the Commission's Guidelines on Horizontal Co-operation Agreements and existing case law (for example, the *Johnson & Johnson/Novartis* case (COMP/39685-Fentanyl) where the Commission concluded the co-promotion agreement was illegal by

object, though that case was very specific to its facts and does not mean that all co-promotion agreements will be considered anticompetitive).

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

Agreements involving the exchange of competitively sensitive information between competitors are likely to raise concerns. The extent of any information exchanged between parties must be carefully considered and appropriate precautions taken (ie, exchange should be limited to historic, aggregated data and confidentiality provisions included).

In some cases, it may be possible to justify cooperation agreements, even between close competitors. Research and development (R&D) agreements that contemplate cooperation covering both joint R&D and the joint exploitation of the results of that R&D, may fall within the R&D Block Exemption Regulation (Commission Regulation (EU) No. 1217/2010) and be valid and enforceable as a matter of EU law. This is likely to be the case where the parties could not have developed and commercialised the relevant product independently of each other and the agreement resulted in a superior product that was brought to market more quickly and more effectively made available to a broader range of potential consumers.

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

The CMA has adopted the previous guidance of the OFT on vertical agreements (which in turn followed the approach of the Commission) – OFT 419 Vertical Agreements. The guidance acknowledges that vertical agreements do not generally give rise to competition concerns. Vertical agreements may benefit from block exemption provided the agreement does not contain any hard-core restrictions (these include resale price maintenance, market partitioning by territory or customers, selective distribution and the supply of spare parts), and the market shares of both the supplier and the buyer are below 30 per cent on the market or markets on which the goods or services covered by the agreement are sold and bought.

Vertical agreements can cause competition problems if one of the parties to the agreement possesses market power or the agreement is one of a number of similar agreements having a cumulative effect on the market (a 'network' effect).

Distribution agreements are an example of a vertical agreement. Distribution agreements are commonly entered into by pharmaceutical companies where a company wants to benefit from the distributor's sales force or distribution network or when originator companies face generic entry, they may wish to launch their own generic either alone or with a generic company.

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

According to the Commission's decisions in *Lundbeck* and *Servier*, patent settlements that are entered into between actual or potential competitors and that contain a 'value transfer' from the originator company to the generic company in return for restrictions on the generic company's entry, will expose the parties concerned to potential liability for antitrust violation. According to the Commission, these types of agreements are 'by-object' infringements of competition law; the most serious type of antitrust violation. This places them in the same category as out-of-scope settlements and those involving sham patents. The Commission's decisions also confirm that generic companies can be considered by the Commission to be potential competitors, even if the originator has valid patents in place or the generic company is experiencing potentially insurmountable regulatory, commercial or manufacturing difficulties in launching a generic product. The definition of a value transfer is very broad and can include monetary payments, the purchase of generic stock for destruction, a distribution agreement, the purchase of technology and a licence to the originator's IP rights. Both the *Lundbeck* and *Servier* Commission decisions were appealed to the General Court.

In September 2016, the EU General Court issued its decision in *Lundbeck* – the first judgment on the legality of reverse payment patent settlement agreements in Europe. It was hoped that the General Court's decision would bring some clarity to the legal standard that applies to reverse payment patent settlement agreements, but the General Court merely upheld the Commission's decision in its entirety. The General Court's decision has now been appealed to the Court of Justice and therefore it will be several years until pharmaceutical companies can obtain any certainty on the legality of reverse payment patent settlement agreements. However, in the meantime, there are some conclusions that can be drawn from the General Court's judgment:

- There are three basic criteria for the finding of a 'by-object' infringement of competition law: (i) a significant 'value transfer' from originator to generic company; (ii) restrictions on the generic company's entry on the market; and (iii) the generic and originator company being actual or potential competitors.
- The size of the 'value transfer' matters. While a payment can be linked to the costs of litigation, if it is linked to the generic company's anticipated profits post-entry, it is likely to be considered anticompetitive.
- The very attempt to conclude an agreement or to engage in discussions with a generic undertaking not yet present on the market provides a strong indication that the generic undertaking is a potential competitor (irrespective of any commercial, legal, and regulatory barriers to entry).
- There is a likelihood that once the compound patent has expired, the competition authorities may treat the market as in principle open to generic companies. Therefore a generic company is more likely to be a potential competitor if the relevant patent is a process patent. The implication is that settling a patent dispute on a compound patent is much less likely to cause concern, but that care should be taken when settling a dispute on a process patent.
- The generic company's internal documents can be used to determine whether the particular generic company was a potential competitor. This would be the case, for example, where the generic company's internal documents indicate that the generic company would be prepared to enter 'at risk' and that it is taking steps to enter the market. On the other hand, any documents that indicate that the generic company considers the patent valid could be useful in proving the absence of potential competition.
- Settlement agreements that are only temporary in nature and do not finally resolve the litigation will be looked at suspiciously.

We are still waiting for the General Court's decision in *Servier*. While unlikely, it cannot be excluded that the General Court may take a different approach in *Servier* than it did in *Lundbeck* given that it will be presented with a different set of facts. For example, in the *Servier* case, unlike in *Lundbeck*, the agreements did finally settle the litigation between the parties.

As mentioned above, the CMA also recently fined GlaxoSmithKline and a number of generic companies for entering into patent settlement agreements involving a value transfer. The CMA's decision in *GSK* largely follows the Commission's approach in the *Lundbeck* and *Servier* cases. The *Servier* and *GlaxoSmithKline* decisions also include a further antitrust violation. As well as the article 101 and Chapter 1 infringement, both Servier and GlaxoSmithKline are alleged to have abused their dominant position under article 102 and Chapter 2 prohibition.

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

The following types of information are likely to be considered 'competitively sensitive' and should not be exchanged between competitors: information related to pricing, production costs, production plans and expectations, innovation and product R&D, and other strategic issues. The exchange of information between competitors in the context of collaboration agreements needs to be carefully managed and must be strictly restricted to information necessary for the joint R&D, production and commercialisation. There is a concern that cooperation arrangements – justified under competition law – can be used (intentionally or inadvertently) as a means for coordinating commercial behaviour in other areas, outside of the scope of the collaboration where the parties are expected to continue to compete independently. This is sometimes referred to as 'the spillover risk'.

Update and trends

There are a number of emerging trends in antitrust regulation and enforcement in the pharmaceutical sector in the UK.

The first key trend is the CMA's focus on pricing practices and regulation. In December 2016, the CMA issued an infringement decision against Pfizer and its distributor Flynn Pharma for charging unfair and excessive prices to the NHS for phenytoin sodium capsules used in the treatment of epilepsy. The CMA's decision is interesting for a number of reasons:

(i) the CMA adopted a very narrow market definition. In order to find the parties dominant it had to define the market at ATC5, that is, the molecule level. This is despite there being alternative medicines for the treatment of epilepsy. In doing so, the CMA relied on the fact that once patients become stabilised on phenytoin sodium capsules they are not usually switched to other products (even to another manufacturer's version of the same product) due to the medical risks associated with switching;
(ii) Pfizer and Flynn pharma were not found to have colluded or to be collectively dominant. Instead, the CMA's case is that they were each dominant;
(iii) the CMA ordered the parties to reduce their prices but did not specify a rate that the parties should use or indicate the scale of price reductions required; and
(iv) the medicine is no longer patent protected and has not been patent protected for a long time. The parties have appealed the CMA's decision to the CAT.

The CMA quickly followed its infringement decision in the *Pfizer/Flynn Pharma* case with a statement of objections against Actavis UK alleging similar behaviour in respect of hydrocortisone tablets, used as a replacement therapy for patients with life-threatening adrenal insufficiency. The statement of objections alleged that Actavis UK began producing a genericised version of hydrocortisone in 2008, and subsequently raised prices over 12,000 per cent compared to the branded version previously sold by another company. As a result, NHS spend on hydrocortisone tablets rose from £522,000 a year prior to 2008, to £70 million a year by 2015.

The CMA is also investigating an unnamed pharmaceutical company in relation to price discounts, and a third company in relation to excessive pricing.

The above cases illustrate that the pharmaceutical sector is currently an area of high interest to the CMA, and that pricing practices are coming under increased scrutiny, despite the challenges to establishing excessive pricing infringements in specialised technical industries such as the pharmaceutical industry. Last year, Dr Michael Grenfell, the CMA's Executive Director for Enforcement, stated that the CMA remains intent on 'tackl[ing] illegal behaviour that is designed to stifle competition at the expense of customers – in this case the NHS and, ultimately, taxpayers'. This shows that this policy is beginning to take effect.

The second key trend is the adoption of very narrow market definitions in pharmaceutical investigations in order to find companies dominant. This is the case even where the company no longer has patents in place. Most of the cases in the pharmaceutical sector in the UK have been abuse of dominance cases requiring the authority to establish dominance in order to pursue these cases. The trend for adopting narrow market definitions in the pharmaceutical sector began with the *AstraZeneca* case and has since been followed in *Servier*, *GlaxoSmithKline* and *Pfizer/Flynn Pharma*.

The third key trend is that the CMA appears to be following the Commission's lead in its scrutiny of the pharmaceutical sector. In fact, it was the Commission that brought the GlaxoSmithKline agreements to the CMA's attention, following which the CMA opened an investigation against GlaxoSmithKline and several generic companies. In view of the number of pharmaceutical cases that the CMA has opened since the *GlaxoSmithKline* case, the scrutiny of the pharmaceutical sector shows no signs of slowing down.

It is unlikely that the measures introduced to increase transparency will make anticompetitive exchanges of information more likely to occur. Pharmaceutical companies are now required to disclose details of payments made to healthcare professionals, or their employers on their behalf, for certain services such as chairing and speaking at meetings, assistance with training and participation in advisory boards. The new system does not cover certain payments to HCPs in relation to R&D work, such as the conduct of clinical trials. Companies will be required to disclose their R&D spending in aggregate. This information is not usually competitively sensitive and should not, therefore, increase the risk of anticompetitive exchanges.

Following a change to the ABPI Code of Practice in 2012, companies are also obliged to publish all clinical trial results within one year of marketing authorisation and publically register new clinical trials within 21 days of the first patient being enrolled. This is in line with the International Federation of Pharmaceutical Manufacturers and Associations Code of Practice. Again, exchanges of this type of information are unlikely to be anticompetitive.

Anticompetitive unilateral conduct

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

The concept of abuse is a wide one: any conduct by a dominant company that allows it to enhance or exploit its market position to the detriment of competitors or consumers may be considered to constitute an abuse. Conduct that has been considered abusive by the competition authorities includes:

- refusal to supply so as to prevent effective competition – or only doing so on a discriminatory basis;
- acquiring competing technologies to exclude competitors;
- concluding exclusive purchasing, supply or distribution agreements so as to create a barrier to entry;
- concluding patent settlement agreements containing certain features with several generic companies;
- tying or leveraging so as to extend the company's dominance from one market into another;
- providing misleading information to the authorities;
- excessive pricing;
- pricing discrimination, predatory pricing and fidelity pricing (ie, discounting); and
- applying discriminatory standards to third parties.

The OFT/CMA found infringements in five Chapter II (article 102) cases: *Napp*, *Genzyme*, *Reckitt Benckiser*, *GlaxoSmithKline*, and *Pfizer/Flynn Pharma* (see question 6).

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

The general EU rules on dominance apply in the UK, and as such, a presumption of dominance may apply with market shares over 50 per cent, and dominance may be assessed at lower levels of market share, although generally not below 40 per cent. In practice, the CMA will take an in-depth economic approach to assessing the existence of dominance, taking into account factors such as barriers to entry (eg, regulatory constraints), the potential for competitors to expand their activities or for new competitors to enter the market, and strength of buyers in the market.

Companies in the pharmaceutical sector are particularly at risk of being found to be dominant. As mentioned above, the ATC system is the starting point for market definition. There are five ATC levels, from ATC1, which is the anatomical main group, to ATC5, which is the chemical substance (ie, individual molecules). Case law usually takes ATC3, which is the therapeutic indication, as the starting point for market definition. However, in *AstraZeneca v Commission* (C-457/10), the General Court used ATC4, which is based on the mode of action, to define the relevant market. The General Court agreed with the Commission that while the analysis generally starts from the ATC3, other ATC levels will be taken into consideration where it appears that sufficiently strong competitive constraints operate at other ATC levels that consequently ATC3 does not allow for a correct market definition.

In the recent case of *Servier*, the Commission took an even narrower approach (in fact, the narrowest approach possible) in defining the relevant market at ATC5 (ie, the molecule level). The CMA has followed this trend by adopting narrow market definitions in the *GlaxoSmithKline* and *Pfizer/Flynn Pharma* cases taking ATC5 (ie, the

molecule level) as the relevant market. This is of significant concern to companies operating in the pharmaceutical sector in view of the special responsibility attached to dominant companies.

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

The fact that a company holds a patent does not necessarily mean that it is in a dominant position, but it is possible that a patent may be seen to confer market power. A detailed assessment will be required in each case. The CMA is likely to consider a range of factors in determining the patent holder's status, including the existence of competitor technologies. For example, as referred to elsewhere, in its finding of abuse of dominance in the *Gaviscon* case in 2011, the OFT referred to market share, but also high barriers to entry that facilitated maintenance of the high market share and were a consequence of patent protection for the branded product.

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

It will not ordinarily be the case that the application for the grant of a patent will give rise to an antitrust violation. However, in the *AstraZeneca Commission* decision and subsequent General Court judgment, it was held that deliberately misleading patent authorities in applying for Supplementary Protection Certificates could amount to a breach of competition law. Pharmaceutical companies must be transparent when dealing with the authorities in respect of IP rights.

It is possible for a patent owner to abuse its dominant position through the enforcement of a patent, but this might only be expected to occur in exceptional circumstances (eg, where the patent owner is enforcing a patent that it knows to be invalid).

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

In general, life-cycle management strategies are not likely to be caught by competition rules. However, the Commission's Pharmaceutical Sector Inquiry Report found that pharmaceutical companies have recourse to a 'toolbox' to delay generic entry, including:

- strategic patenting;
- patent litigation;
- patent settlements;
- interventions before national regulatory authorities;
- promotional activities; and
- life-cycle strategies for follow-on products.

In some cases, the above practices can expose the patent owner to antitrust liability. As noted above, the Commission and the CMA have fined companies (including Servier and GlaxoSmithKline) for entering into patent settlement agreements. However, it is not always the case that such practices will be anticompetitive. For example, life-cycle management strategies for follow-on products, such as product switching and product hopping, appear to be acceptable as long as the old product is replaced with one that incorporates innovations that are valued by clinicians and patients. In *Reckitt*, the second generation product was not innovative, as was clear by the internal documents seized by the OFT, which showed the withdrawal of the original product was motivated only by a desire to hinder competition in the relevant market. It is clear from previous cases that internal documents showing the company's intention can be determinative for a competition authority.

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

Originator companies may launch their own generic either alone or by agreement with a third party. If they launch by agreement with a third party, the third party acts as a distributor.

In its Final Report of the Pharmaceutical Sector Inquiry published in July 2009, the Commission suggested that it may in future examine early entry agreements (agreements for the introduction of a generic product onto the market before the expiry of the patent protection). The question as to whether authorised generics enhance competition on the generic medicines market by offering competition to new entrant generics following patent expiry therefore remains open and to be determined on the facts of specific cases. Such arrangements could give rise to competition law risks where the originator company is dominant or where the parties to the agreement are actual or potential competitors.

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

Specific features of the sector are unlikely to objectively justify otherwise anticompetitive behaviour.

However, there are specific features of the pharmaceutical sector that must be considered by the competition authorities when applying competition law to the pharmaceutical sector.

First, the protection of intellectual property rights (such as the application and enforcement of patents) is fundamental to the profitability and success of a pharmaceutical company. Intellectual property rights are key to the promotion of innovation. While this may be true for a number of sectors, the European Commission has acknowledged that it is of particular relevance to the pharmaceutical sector. The exclusivity periods granted through patent law and other mechanisms (eg, SPC, data exclusivity, paediatric extensions) provide incentives to originator companies to continue innovating. There is, therefore, a need to ensure that innovation is not stifled by short-term considerations such as keeping prices low. Extensive intervention by competition authorities can potentially stifle innovation, which would have a negative impact on social and economic welfare. The European Commission has stated that at the highest levels competition law and intellectual property rights are complementary. However, in practice, it is easy to see how these two areas of law can conflict.

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Secondly, the market dynamics are unique in the pharmaceutical sector. Unlike in other markets, the decision-maker, payer and consumer are not the same person. In the UK, the decision-maker is the doctor, the payer is the National Health Service, and the consumers are the patients, all of which have competing interests that need to be appropriately balanced.

Thirdly, the market for the sale and supply of pharmaceutical products is national. For example, pricing and reimbursement and the organisation of social security systems generally is a competency of member states, meaning that it is for member states to determine the treatments they wish to reimburse and the conditions under which those treatments are to be reimbursed. These national pharmaceutical markets exist in a context in which competition law has as its main aim the creation and maintenance of a single market. There have been a number of parallel trade cases that highlighted this tension and where the EU courts have held that any agreements that are aimed at dividing national markets, such as those aimed at preventing or restricting parallel trade, will infringe competition rules.

The authorities have and continue to take a tough stance against pharmaceutical companies and are not necessarily persuaded by arguments concerning the specific features of the pharmaceutical sector. In *Napp*, for example, the OFT rejected arguments that the pricing of medication could not be deemed excessive because it was subject to regulation by the PPRS. The OFT found that the fact Napp did not exceed the limit on return of capital allowable under the PPRS across the range of its products was not a defence to a charge of excessive pricing under Chapter II (see question 8). In *Servier* the Commission was similarly not convinced by arguments concerning the specific features of the pharmaceutical sector when applying competition law to patent settlement agreements.

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

National enforcement activity in relation to life-cycle management and settlement agreements with generics has certainly increased since the EU Sector Inquiry.

The OFT/CMA has adopted decisions against *Reckitt* for product switching, against *GlaxoSmithKline* and several generic companies for entering into patent settlement agreements, and against *Pfizer* and *Flynn Pharma* in relation to their pricing practices. The CMA's activity in this sector is likely to continue, as is explained in 'Update and trends'.

United States

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

Approving pharmaceutical products

The Federal Food, Drug, and Cosmetic Act (FFDCA) regulates small molecule drugs and establishes processes for bringing new drugs to market. For innovator (brand-name) drugs, a new drug application (NDA), requiring proof that a drug is safe and effective and that the benefits of the drug outweigh the risks, must be submitted to the Food and Drug Administration (FDA). For generic drugs, an abbreviated new drug application (ANDA), requiring proof that the product is the same as, and bioequivalent to, an already approved product, must be submitted. The FDA publishes a list of drugs already approved under the FFDCA – 'Approved Drug Products with Therapeutic Equivalence Evaluations' – more commonly known as the 'Orange Book'.

The Drug Price Competition and Patent Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) establishes the process for approving generic drugs and is intended to protect innovator drug patents while providing a process for making generic equivalents available as soon as the patent exclusivity period expires. To accomplish this, the Act provides for three- or five-year periods of patent exclusivity for innovator drugs and a process for litigating patent claims before the FDA approves a generic equivalent. It also provides a 180-day period of market exclusivity to the first generic applicant to challenge a listed patent.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 revised rules regarding certain approval stays and exclusivities under the Hatch-Waxman Act. It requires innovator and generic companies that enter into certain types of litigation settlements to file copies of their agreement with the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ).

In contrast, over-the-counter (OTC) drugs are approved under a monograph system. The FDA reviews the active ingredients of over 80 therapeutic classes of drugs and, for each category, develops a drug monograph. Once finalised, these monographs are published in the Federal Register. Companies that make and market OTC products conforming to a final monograph do not need to seek pre-approval from the FDA. Products that do not conform, however, must be approved through the NDA or ANDA application process.

The Public Health Service Act (PHSA) regulates biologics and establishes a separate process for bringing biologics to market. Innovator (brand name) biologics are approved via a Biologics License Application, which requires proof that a biologic is safe and effective. The Biologics Price Competition and Innovation Act of 2009 (BPCIA) creates an abbreviated approval process for approving 'biosimilars', which are biologic drugs that are similar, but not identical, to FDA-licensed biologics. The FDA publishes a list of biologics already licensed under the PHSA and any interchangeable biosimilars, commonly known as the 'Purple Book'.

Biosimilar applicants must demonstrate that the product is safe and effective, but can rely on previous FDA findings for similar, licensed products. Applicants must, however, provide additional data and seek a separate finding by the FDA before the product can be approved as a biosimilar. Like the Hatch-Waxman Act, the BPCIA provides periods of market exclusivity for innovator biologics and the first biosimilar applicant. Under the BPCIA, a biosimilar application cannot be submitted to the FDA until four years after the date of the innovator product's licensure and may not be approved until 12 years after such date. In addition, the first biosimilar applicant is itself eligible for an exclusivity period of 12 months. However, that exclusivity period may be extended if, for example, patent litigation under the PHSA remains pending.

Marketing pharmaceutical products

The FFDCA regulates the advertising and promotion of prescription drugs and biologics and the Federal Trade Commission Act (the FTC Act) regulates the advertising and promotion of OTC drugs. Both Acts prohibit making false and misleading representations regarding pharmaceutical products. The FDA is responsible for enforcement of the FFDCA and the FTC is responsible for enforcement of the FTC Act.

The federal Anti-Kickback Statute makes it a felony for any individual or entity to solicit or receive anything of value in exchange for influencing a federal health-care beneficiary to use a particular drug.

The Physician Payments Sunshine Act provisions, enacted as part of the Affordable Care Act, also require that drug manufacturers who sell products eligible for federal healthcare reimbursement report to the Centers for Medicare and Medicaid Services (CMS) certain payments or items of value given to physicians and teaching hospitals. CMS aggregates reported data and then publishes it annually on a public website.

Pricing pharmaceutical products

In general, the United States does not regulate the pricing of pharmaceutical products purchased by commercial payers and private individuals. It does, however, impose special pricing rules in the context of certain federal health programmes such as Medicare and Medicaid.

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

At the federal level, the distribution of pharmaceutical products is governed by the Prescription Drug Marketing Act, as amended. The Act requires each person engaged in wholesale distribution of prescription drugs who is not the manufacturer or an authorised distributor of record for the drug, to provide a statement to the person receiving the drug identifying each prior sale, purchase or trade of the drug, along with other information.

Drug wholesalers also must be licensed under state licensing systems and meet certain minimum requirements for the storage, security and handling of prescription drugs, including the treatment of returned, damaged and outdated drugs.

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

As described in greater detail below, the Hatch-Waxman Act provisions that regulate the approval and entry of generic drugs generally have had the greatest impact on competition in the pharmaceutical sector. Enforcers and private plaintiffs have alleged that brand-name pharmaceutical manufacturers have abused or improperly manipulated this process to delay or restrict generic entry or enter into anticompetitive

patent litigation settlements. The BPCIA is only now being put into force; it remains to be seen to what extent it creates situations similar to what has occurred under the Hatch-Waxman Act.

Competition legislation and regulation

4 Which legislation sets out competition law?

The principal federal competition statutes in the United States are the Sherman, Clayton, FTC and Robinson-Patman Acts. Section 1 of the Sherman Act prohibits unreasonable restraints of trade, including per se illegal agreements such as price fixing and market allocation, as well as other forms of agreements that are evaluated under the 'rule of reason'. Section 2 of the Sherman Act prohibits certain unilateral conduct, including obtaining or maintaining a monopoly through predatory or exclusionary means.

Mergers and acquisitions are regulated by section 7 of the Clayton Act and the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the HSR Act). The Clayton Act prohibits mergers and other acquisitions 'where the effect . . . may be substantially to lessen competition or tend to create a monopoly in any line of commerce'. The HSR Act requires companies to notify the DOJ and FTC in advance of any planned mergers or acquisitions (or certain joint ventures) exceeding certain size thresholds and to observe a waiting period. The FTC Act authorises the FTC to bring enforcement actions against 'unfair methods of competition' and 'unfair or deceptive acts or practices' and generally prohibits the same types of conduct that would violate the Sherman Act. The Robinson-Patman Act prohibits certain forms of price discrimination in the sale of commodities, including pharmaceuticals, to resellers or distributors.

The vast majority of states have adopted antitrust laws, most of which are modelled on the federal antitrust laws or are interpreted consistently with their federal counterparts, although some substantively differ from federal antitrust law.

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

The FTC and DOJ (the Antitrust Agencies) share the responsibility of enforcing US federal antitrust laws. The agencies utilise an informal process based on each agency's expertise to allocate responsibility between them for particular investigations. The DOJ, however, has the sole authority to prosecute criminal antitrust matters such as price fixing and bid rigging. In practice, non-criminal matters relating to the pharmaceutical industry are generally handled by the FTC, making it the primary federal antitrust enforcement body for pharmaceutical companies. State attorneys general can enforce both state and federal antitrust laws on behalf of residents, as well as pursue claims on behalf of the state with respect to purchases by state agencies.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

Criminal violations of the Sherman Act are generally punishable by fines of up to US$100 million for a corporation and US$1 million for an individual, although those fines may be increased to twice the amount gained by the conspirators or double the amount lost by the victims. Individuals also may be sentenced to imprisonment for up to 10 years. For civil antitrust violations, the DOJ and FTC may seek civil penalties of up to approximately US$40,000 per day and injunctive relief and, in some circumstances, the disgorgement of ill-gotten gains. Divestitures are the most common remedy for merger-related anticompetitive conduct. HSR-related and other procedural violations are generally punishable by civil penalties.

For example, in the merger control area, the FTC required Mylan NV (Mylan), to divest assets and marketing rights for 400 mg and 600 mg generic felbamate tablets, which treat refractory epilepsy and 250 mg generic carisoprodol tablets, which treat muscle spasms and stiffness, in order to proceed with its acquisition of Meda AB (Meda). Mylan and Meda were three of only four competitors in the market for 400 mg and 600 mg generic felbamate tablets. Only two firms marketed generic carisoprodol, but Mylan had recently received FDA approval to market a generic carsioprodol product. In addition to Meda, only one other firm marketed a generic carisoprodol product, and Mylan had recently received FDA approval to market a generic carisoprodol product. As a result, the acquisition would have eliminated the entry of a third market participant. (*In the matter of Mylan NV*, FTC File No. 161-0102, https://www.ftc.gov/system/files/documents/cases/160908mylanmedacmpt.pdf.)

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Private parties can sue for injunctive and monetary relief under the Clayton Act. The monetary relief available to a private plaintiff can be significant, as the Clayton Act provides for treble damages and the recovery of attorneys' fees and costs for successful plaintiffs. While federal law allows only direct purchasers of goods and services to recover damages for antitrust violations (*Illinois Brick Co v Illinois*, 431 US 720 (1977)), many states allow indirect purchasers to recover for antitrust violations under state antitrust law. Private antitrust suits in the US often take the form of class action lawsuits (see *In re Plasma-Derivative Protein Therapies Antitrust Litig*, 2012 US Dist LEXIS 2501 (ND Ill 2012) (holding that an indirect purchaser of plasma-derivative protein therapies lacked antitrust standing under the Sherman Act and, therefore, could not seek damages, but instead only injunctive relief)).

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

In general, the Antitrust Agencies only issue subpoenas when there is cause to believe that there has been a legal violation. While there has been no sector-wide inquiry into the pharmaceutical industry to date, in May 2015 the FTC issued a staff report on competition in the pet medications industry (see Competition in the Pet Medications Industry, FTC Staff Report, www.ftc.gov/system/files/documents/reports/competition-pet-medications-industry-prescription-portability-distribution-practices/150526-pet-meds-report.pdf).

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

Non-government organisations can play an important role in providing input to the competition authorities, either by informing the authorities about a potential competition issue, or by providing input (either voluntarily or in response to the authorities' request) with respect to an ongoing investigation of a specific conduct or merger. The most weight, however, is given to information furnished by market participants, especially customers, directly affected by the conduct at issue. Private antitrust litigation can only be brought by parties that have standing, which requires that they be directly affected by the challenged conduct and have sustained the kind of injury that the antitrust laws were designed to prevent.

Review of mergers

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

The FTC and DOJ apply the same substantive test to the analysis of a proposed merger, regardless of industry, with the Horizontal Merger Guidelines (the Merger Guidelines) providing the framework for the agencies' review. The agencies do, however, take the specific features of a market into account when analysing the competitive effects of a transaction, and the highly regulated nature of the pharmaceutical market is an important part of the analysis in a pharmaceutical transaction.

Entry that is timely, likely and sufficient to counteract anticompetitive effects can be a defence to the assertion that a merger will substantially reduce competition. Entry into the pharmaceutical industry can be time-consuming and expensive, however, because of the regulatory approval process for new drugs. Thus, the FTC generally has taken the position that de novo entry into a pharmaceutical product market will not be timely because of a combination of drug development times and FDA approval requirements (eg, *In the Matter of Hikma Pharmaceuticals PLC*, FTC File No. 1510198, www.ftc.gov/system/files/documents/cases/160226hikmacmpt.pdf).

In reviewing mergers of generic pharmaceutical manufacturers, the FTC has taken into account the merging firms and their competitors' ability to compete for new generics during the initial 180-day marketing exclusivity period. For example, in connection with Teva's acquisition of Cephalon, the FTC required Teva to extend its supply agreement with Par, enabling Par to continue to compete during the initial 180 days, and to enter into a licensing agreement with Mylan to establish an independent competitor to Teva after the exclusivity period had ended (*In the Matter of Teva Pharmaceuticals Industries Ltd and Cephalon Inc*, FTC File No. 111 0166, www.ftc.gov/os/caselist/1110166/index.shtml).

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

When defining a relevant pharmaceutical market, the Antitrust Agencies focus on the nature of the transaction and specific products at issue. The ultimate question with respect to market definition is to what alternatives customers could turn in the face of an attempted price increase by the merged firm. In the pharmaceutical sector, the relevant product market is sometimes defined by the illness or condition that the drug is approved to treat (eg, *In re Pfizer and Pharmacia*, FTC File No. 021-0192, www.ftc.gov/os/2003/04/pfizercmp.htm; one relevant market defined as drugs for treatment of erectile dysfunction). In other instances, the agency will define a market based on the particular mechanism by which the pharmaceutical works or the manner in which it is administered (eg, *In the Matter of Novartis AG*, FTC File No. 141-0141, www.ftc.gov/system/files/documents/cases/150408novartiscmpt.pdf; two separate relevant markets defined for BRAF and MEK inhibitors, cancer treatment drugs that inhibit molecules associated with the development of cancer). Product markets in some cases have been limited to a specific drug and its generic substitutes, but even more commonly, solely to the generic form of a particular drug (eg, *In the Matter of Teva Pharmaceutical Industries and Barr Pharmaceuticals*, FTC File No. 081-02224, www.ftc.gov/os/caselist/0810224/081219cmp0810224.pdf).

The FTC has said that where a 'branded drug manufacturer may choose to lower its price and compete against generic versions of the drug', the brand 'is a participant in the generic drug market' (*In the matter of Mylan Inc, Agila Specialties Global Pte Limited, Analysis of Agreement Containing Consent Orders to Aid Public Comment*, FTC File No. 131-0112, www.ftc.gov/sites/default/files/documents/cases/130926mylananalysis.pdf).

The Antitrust Agencies generally define the relevant geographic market in a pharmaceutical merger to be the United States because of the country's regulatory scheme for drug approvals and sales.

12 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

US courts and Antitrust Agencies generally do not take into account industrial policy arguments when considering whether a merger or conduct violates the antitrust laws. Evidence that a merger or other challenged conduct will create efficiencies that result in lower costs, improved quality, or increased innovation, however, is typically relevant to the antitrust inquiry. Evidence of the pro-competitive benefits of the challenged conduct will weigh in favour of a finding of lawfulness.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

Under the agencies' 2010 Horizontal Merger Review Guidelines, the focus of a merger analysis is whether the merger will 'encourage one or more firms to raise prices, reduce output, diminish innovation, or otherwise harm customers as a result of diminished competitive constraints or incentives'. In reviewing a merger, the US Antitrust Agencies generally follow the 2010 Horizontal Merger Review Guidelines, which identify two types of potential anticompetitive effects – unilateral and coordinated.

Unilateral effects result from the elimination of competition between the two merging firms that allows the merged firm to unilaterally raise prices. The analysis hinges on the degree to which the products of the merging firms are reasonable substitutes for each other, and the agencies use a variety of indicia to assess their substitutability. Views of physicians, evidence of switching by physicians or patients in response to price or other factors and other evidence of head-to-head competition, such as competition for favourable placement on a payer's formulary, may be relevant to the analysis. The more closely the products of the merging companies compete, the more likely it is that the merged firm will be able to profitably raise prices above competitive levels because sales lost because of a price increase will more likely flow to the merger partner. The agencies also rely heavily on the merging parties' ordinary course documents for evidence of an anticompetitive rationale for a transaction.

Under a coordinated effects analysis, a merger may be anticompetitive if it facilitates coordination among competitors. A market is susceptible to coordinated conduct when a number of characteristics are present, including a small number of firms, observable actions of competitor firms, the possibility of quick responses by rivals to a firm's competitive actions, a history of collusion, small and frequent sales in the market and inelastic demand.

In *Grifols/Talecris*, the FTC alleged both unilateral and coordinated effects, stating that the combined company would be able to unilaterally increase prices without experiencing a reduction in demand. The FTC also alleged that the transaction would facilitate coordinated interaction between the combined company and other market participants because of the characteristics of the industry and the fact that there had been prior allegations of collusion in the industry (*In the Matter of Grifols SA and Talecris Biotherapeutics Holdings Corp*, FTC File No. 101-0153, www.ftc.gov/os/caselist/1010153/110601grifolsacmpt.pdf).

In reviewing a merger of two firms, the Antitrust Agencies will evaluate all of the products marketed by both firms to determine if there is an overlap, as well as the pipeline portfolio of each firm to determine whether the firms are developing any potentially competitive products. The agencies will consider problematic any merger that is likely to enable the merged firm to raise prices unilaterally in one or more relevant market or to facilitate coordination among the merged firm and remaining competitors in one or more relevant market.

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

An overlap between a currently marketed product and one in development can raise concerns where there are few substitute products either on the market or being developed by other firms, the product in development appears likely to receive FDA approval and the products are close substitutes for one another. For example, the FTC has challenged mergers where neither firm currently competes in a market, but both firms are viewed as future entrants (eg, *In the Matter of Lupin Ltd, Gavis Pharmaceuticals Inc and Novel Laboratories Inc*, FTC File No. 151-0202, www.ftc.gov/system/files/documents/cases/160219lupingaviscmpt.pdf; acquisition alleged to eliminate future competition in the market for a generic extended release capsule used to treat colitis where Gavis and Lupin were two of a limited number of suppliers capable of entering the market). Both actual and potential competition are analysed using the framework of the Merger Guidelines.

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

The DOJ and FTC have stated a strong preference for structural remedies (ie, divestitures) over conduct remedies that require monitoring. In the event that a divestiture is required, the agencies will seek to ensure that the purchaser of the divested asset has everything needed to become an effective competitor. As a result, the divestiture of a complete business unit is generally preferred, and the agencies may require that the merging parties divest both tangible assets, such as manufacturing facilities, and intangible assets, such as research and development or intellectual property. The agencies also have mandated licensing arrangements in connection with a divestiture. For example, the FTC's consent order in *Grifols/Talecris* mandated a combination of divestitures and a licensing arrangement to Kedrion, an Italian company (*In the Matter of Grifols, SA and Talecris Biotherapeutics Holdings Corp*, FTC File No. 101-0153, www.ftc.gov/os/caselist/1010153/110722grifolsdo.pdf; requiring the divestiture of a fractionation facility,

a haemophilia treatment business and a seven-year manufacturing agreement with the purchaser of the divested assets).

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

The acquisition of a patent or exclusive licence may be subject to the HSR Act reporting requirements if the value of the patent or exclusive licence meets the threshold requirements for pre-merger notification, and the transaction is not otherwise exempt.

The HSR thresholds include both a size-of-transaction and size-of-persons test. Under the size-of-transaction test, the threshold is met when a buyer acquires, or will hold as a result of an acquisition, voting securities, assets or non-corporate interests valued in excess of US$80.8 million. If the value of the transaction is greater than US$323 million, the transaction is reportable even where the size-of-persons test is not satisfied. Under the size-of-persons test, the threshold is met if one party to the transaction has at least US$161.5 million in annual sales or total assets and the other has at least US$16.2 million in annual sales or total assets. (These dollar values are for 2017; the dollar value of these thresholds is revised annually based on changes in the US gross national product.)

In 2013, the FTC implemented a new HSR rule that clarifies when the transfer of rights to a patent in the pharmaceutical sector is reportable under the HSR Act as an asset transfer and expands the application of the HSR Act to certain exclusive licences in the pharmaceutical sector. Specifically, the rule targets licensing agreements that transfer the exclusive use and sale of a patent, but allow the licensor to retain manufacturing rights for that patent. Under the new rule, a transfer of 'all commercially significant rights' to a pharmaceutical patent is reportable if it otherwise meets the HSR Act's size-of-transaction and size-of-person thresholds. 'All commercially significant rights' is defined as 'the exclusive rights to a patent that allow only the recipient of the exclusive patent rights to use the patent in a particular therapeutic area (or specific indication within a therapeutic area)'. Such a transfer now occurs even if the patent holder retains the right to manufacture solely for the recipient (licensee) or retains the right to assist the recipient in developing and commercialising products covered by the patent.

This patent transfer reporting rule applies only to the pharmaceutical sector, distinguishing it from other industries in the treatment of the transfer of exclusive licences where the transferor retains a right to manufacture. The new rule was upheld by the United States Court of Appeals for the District of Columbia in 2015 (*Pharmaceutical Research and Manufacturers of America v FTC*, No. 1:13-cv-01974 (DC Cir 9 June 2015)).

Anticompetitive agreements

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

Under section 1 of the Sherman Act, agreements that unreasonably restrict trade are prohibited, with agreements among competitors receiving the closest scrutiny. Certain 'horizontal' agreements (eg, price fixing or market allocation) are considered illegal per se, meaning that the plaintiff need not define the affected relevant market or prove anticompetitive effects, and the defendant does not have the opportunity to put forward justifications for the agreement. Horizontal agreements that are reasonably necessary to achieve efficiencies are judged under the 'rule of reason', where the agreement's pro-competitive benefits are weighed against its anticompetitive effects within the relevant product and geographic markets.

Vertical agreements, such as those between suppliers and customers, are more likely to have legitimate business justifications and less likely to have anticompetitive effects than horizontal arrangements, and therefore generally are judged under the more lenient rule of reason. In the pharmaceutical industry, antitrust enforcers have applied close antitrust scrutiny to agreements that have the effect of restricting or delaying generic competition. These so called 'pay-for-delay' cases are discussed in greater detail below.

Section 2 of the Sherman Act also prohibits exclusionary or predatory conduct by firms with monopoly power or a dangerous probability of achieving a monopoly. Pharmaceutical companies are at particular risk of challenges under section 2 because they may be accused of having a monopoly position in a narrowly defined product market, perhaps limited to a single product (see question 24 et seq).

18 To what extent are technology licensing agreements considered anticompetitive?

Technology licensing agreements are generally analysed under the rule of reason, in which the agreement's pro-competitive benefits are weighed against its potential anticompetitive effects. If, however, a court or agency concludes that a licensing agreement is merely a means towards accomplishing a per se illegal objective (eg, a market allocation scheme), then the per se rule might be applied. In 1995, the Antitrust Agencies published Antitrust Guidelines for the Licensing of Intellectual Property (the IP Guidelines), which set forth the Antitrust Agencies' analytical approach. For licensing agreements that are not subject to per se condemnation, the IP Guidelines provide for a safe harbour where the parties involved have no more than a 20 per cent share of each market affected by the licensing arrangement.

Restrictions in licensing agreements can create antitrust risk. Exclusivity provisions, for example, may be challenged if they foreclose competition unreasonably. Courts assessing the foreclosure effect of such agreements examine the term and scope of the exclusivity, the market share of the parties, the business justifications for the exclusivity and the availability of less restrictive alternatives. A requirement that the licensee acquire other products or licences from the licensor as a condition for obtaining the licence can also raise antitrust issues.

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

Co-promotion and co-marketing agreements, like other joint ventures or competitor collaborations, are analysed under the rule of reason. The Antitrust Agencies' Antitrust Guidelines for Collaboration Among Competitors explain how they evaluate these types of agreements. To determine whether an agreement is a legitimate competitor collaboration entitled to rule of reason treatment, an agency or court will look first to whether the agreement integrates the resources of the companies to develop potential efficiencies. For example, a joint marketing or promotion agreement might result in the combination of complementary assets that permits the participants to commercialise products faster or more efficiently. These types of arrangements are likely to be considered lawful under a rule-of-reason analysis as long as the pro-competitive benefits outweigh the likely anticompetitive effects. If, however, the arrangement will merely make it easier for the participants to exercise market power or increase prices, or if the potentially anticompetitive effects outweigh the efficiency-enhancing aspects of the arrangement, then the arrangement may violate antitrust laws.

In addition, as discussed below, the FTC has challenged co-promotion and co-marketing agreements between brand name and generic pharmaceutical companies in connection with patent settlements.

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

Joint ventures among competitors carry possible antitrust risks. The FTC and DOJ have investigated research joint ventures, production joint ventures and joint-purchasing arrangements, among others. All of these types of agreements raise more significant antitrust risks when the participants have a high combined market share. Courts and agencies are especially concerned about restrictions in collaboration agreements that may impact competition outside the scope of the collaboration and are not reasonably necessary to achieve the arrangement's pro-competitive effects.

Even if there is no direct agreement to reduce competition outside of the collaboration, information obtained by the participants as a result of the collaboration sometimes can have 'spillover effects' that reduce competition between the participants. In some cases these spillover effects can outweigh the pro-competitive effects of the collaboration. Companies entering into competitor collaborations can reduce antitrust risk by limiting the participants' access to competitively sensitive information from the other party or the joint venture.

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

Vertical agreements are generally evaluated under the rule of reason and typically raise antitrust issues when they have the effect of foreclosing competitors from a significant portion of the market. For example, if a dominant seller enters into an exclusive arrangement with customers or suppliers that accounts for more than 30 per cent of the relevant market, it may become more difficult for competitors of the seller to compete. 'Loyalty discounts' that condition a customer's receipt of discounts on purchasing most or virtually all of its volume from the seller can have similar foreclosure effects and have been challenged.

Tying arrangements can raise similar antitrust issues and are one of the few vertical restrictions that are at least technically considered illegal per se. Tying occurs where a seller requires a purchaser of one product or service (the tying product) to also purchase a second product or service (the tied product). Where the seller has market power in the tying product, such an arrangement can foreclose competition from rivals selling products that compete with the tied product.

Bundled discounts may have similar effects where they require a customer that purchases one product to purchase a bundle of products in order to obtain a discount on the product that the customer wants. Bundled discounts, however, are a highly unsettled area of US antitrust law, with courts applying different standards to determine when a bundled discount is unreasonably exclusionary (compare *Cascade Health Solutions v PeaceHealth*, 515 F3d 883 (9th Cir 2008) – conduct is exclusionary where bundled discounts result in prices below an appropriate measure of defendant's costs); *LePage's Inc v 3M Co*, 324 F3d 141 (3d Cir 2003) (en banc) – allowing a monopolisation claim to proceed based solely on potential for exclusion, without requiring evidence of below-cost pricing; and *Ortho Diagnostics Sys Inc v Abbott Lab Inc*, 920 F Supp 455 (SDNY 1996) – requiring evidence that bundled discounts led to prices below the defendant's average variable costs and that the plaintiff was at least as efficient a producer of the competitive product). Moreover, although the FTC has relied on the Ninth Circuit's approach in pursuing an enforcement action, it has stated that it retains the right to pursue claims against any alleged monopolist based on a different legal standard, including the Third Circuit's approach that requires no evidence of below cost pricing (*In the Matter of Intel Corporation*, FTC File No. 061-0247, www.ftc.gov/sites/default/files/documents/cases/2010/08/100804intelanal_0.pdf).

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

Settlements of patent litigation between brand-name and generic pharmaceutical companies may create antitrust risk where the agreement has two elements: the generic company agrees to wait until a certain date to enter the market and a payment of some form is made by the brand-name manufacturer to the generic manufacturer. These types of arrangements have been referred to as 'pay for delay' or 'reverse payment' patent settlements and the FTC has taken the position that they result in a payment to the generic manufacturer in exchange for an agreement to delay entry.

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

There is natural tension in pharmaceutical merger discussions that may create a greater possibility of anticompetitive information exchanges. Unlike other sectors, where current product offerings represent the bulk of the value of a company, much of the real or perceived value of a pharmaceutical company is in its pipeline of future products. The importance of the pipeline creates a situation where potential buyers have a real business need to determine the value of a target's pipeline, while also needing to be mindful of anticompetitive exchanges of the target's most competitively sensitive information.

Anticompetitive unilateral conduct

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

Exclusionary or predatory conduct carried out by a firm with monopoly or market power may be unlawful under section 2 of the Sherman Act, which prohibits monopolisation, attempts to monopolise and conspiracies to monopolise. Vertical restrictions that limit competitors' access to supplies or customers, such as exclusive dealing, tying, or loyalty or bundled discounts, may violate the Act. Other types of conduct that have been deemed predatory or exclusionary include predatory (below-cost) pricing, engaging in baseless litigation for an anticompetitive purpose, abusing an industry standard-setting process (eg, by influencing an association to adopt a standard that is designed to suppress competition) and, in rare cases, a refusal to deal with a competitor. Section 2 does not prohibit the mere possession of monopoly or market power or the acquisition of such power through lawful competition on the merits.

In January 2017, Mallinckrodt ARD Inc (Mallinckrodt) and its parent company Mallinckrodt plc agreed to pay US$100 million to settle charges by the FTC and five states that Mallinckrodt illegally maintained its monopoly of Acthar, a specialty drug used to treat a rare seizure disorder affecting infants. According to the FTC, Mallinckrodt violated US antitrust laws when its Questcor division illegally acquired the US rights to develop Synacthen Depot (Synacthen), a drug that threatened Mallinckrodt's existing monopoly in the US market for adrenocorticotropic hormone (ACTH) drugs used to treat infantile seizures. The FTC charged that Mallinckrodt had taken advantage of its monopoly in the market for ACTH drugs by raising the price per vial from US$40 per vial in 2001 to more than US$34,000 per vial today. According to the complaint, Mallinckrodt felt threatened that a competitor would obtain the US rights to Synacthen, a competing drug used in Europe and Canada to treat infantile seizures. In order to maintain its monopoly, Mallinckrodt allegedly outbid several competitors to obtain the US rights to Synacthen from Novartis AG. In addition to the US$100 million fine, Mallinckrodt agreed to grant a licence to develop Synacthen to a licensee approved by the FTC. (*In the Matter of Mallinckrodt ARD Inc, Complaint for Injunctive and Other Equitable Relief*, FTC File No. 131-0172, www.ftc.gov/system/files/documents/cases/170118mallinckrodt_complaint_public.pdf).

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

A party is likely to be considered dominant – that is, to have monopoly power – when it has the ability to control or exclude competition in a 'relevant market'. Courts frequently use a party's market share in a relevant market as a proxy for assessing whether that party has market power. No bright line rules exist for what constitutes monopoly power under US law, but most successful monopolisation claims involve market shares of at least 70 per cent. To succeed on a claim for 'attempted monopolisation', the plaintiff must show that the defendant has a 'dangerous probability' of obtaining monopoly power, which generally requires a market share of at least 50 per cent. US antitrust law does not recognise joint dominance of a market in section 2 cases.

Market share is not, however, the sole determinant of whether a firm has monopoly power. A firm with a high market share may not have monopoly power if there are no or weak barriers to entry and the threat of such entry prevents the firm from acting anticompetitively. Additionally, market power may be proved by direct evidence in the absence of proof that the defendant has a high market share.

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

Generally, no. In *Illinois Tool Works Inc v Independent Ink Inc*, 547 US 28 (2006), the US Supreme Court ruled that a patent holder is not presumed to have market power simply because it holds a patent.

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

Application for the grant of a patent does not, by itself, expose the patent owner to antitrust liability. Enforcement of a fraudulently obtained

patent, however, may violate section 2 of the Sherman Act if used to exclude lawful competition from the market (*Walker Process Equipment Inc v Food Machinery & Chemical Corp*, 382 US 172 (1965)).

In addition to enforcement of a fraudulently obtained patent, a patent owner can be liable for an antitrust violation if it pursues patent litigation with no reasonable chance of success, solely to cause direct harm to the competitor's business as a result of the litigation process. The FTC has also taken the position that the refusal of brand-name pharmaceutical companies to sell samples of their products to generic companies for bioequivalence studies in situations where FDA-imposed distribution restrictions have prevented the generic company from making use of alternative channels to acquire such samples can constitute exclusionary conduct (see FTC's brief as amicus curiae in *Mylan Pharmaceuticals Inc v Celgene Corporation*, Case No. 2:14-CV-2094 (DNJ 2014), available at www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf). In its brief, the FTC argued that Celgene's choice as to with whom it does business was not absolutely shielded from claims like Mylan's. Generic manufacturers often seek these samples from brand-name pharmaceutical companies because they may be necessary to obtain regulatory approval for a generic product. In February of 2015, the Third Circuit declined to reverse the district court decision allowing the case to proceed (*Mylan Pharmaceuticals Inc v Celgene Corporation*, No. 2-14-cv-02094 (3d Cir 27 Feb 2015)).

28 Can certain life-cycle management strategies also expose the patent owner to antitrust liability?

Manufacturers whose branded products are coming off-patent often seek to improve their products, patent the improvement and move their customers to the improved products. There have been several antitrust challenges to this type of conduct, sometimes referred to as product hopping, where it has been alleged that the new drug did not reflect any real improvements and was solely used as an effort to thwart generic competition (eg, *In re Tricor Direct Purchaser Antitrust Litigation*, No. 05-340 (D Del 9 March 2009); Abbott Laboratories and co-defendants settled product-hopping and related claims for US$250 million after losing a motion for summary judgment).

Patent owners also may be subject to antitrust scrutiny for improperly listing patents in the Orange Book as a means to extend exclusivity and thereby impede generic competition (eg, *In the Matter of Bristol-Myers Squibb Co*, Docket No. C-4076 (2003), www.ftc.gov/os/caselist/c4076.shtm). Similarly, drug manufacturers can be subject to antitrust liability for filing a citizen petition with the FDA that is intended solely to delay or prevent competition with the drug and is not based on a reasonable chance of success.

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

Although US law grants 180 days of exclusivity to the first generic drug to reach the market through a patent challenge, that exclusivity does not preclude a brand name manufacturer from launching an authorised generic during the 180-day exclusivity period. Nevertheless, the FTC is increasingly concerned that brand-name pharmaceutical manufacturers are using the threat of launching an authorised generic to delay generic companies bringing their drugs to market.

As noted above, the FTC views a promise by the brand-name manufacturer not to launch an authorised generic to constitute an unlawful 'reverse payment' if included as part of a patent settlement that delays generic entry. In June 2015, the Third Circuit adopted the FTC's position that a commitment not to launch an authorised generic may be a reverse payment under Actavis. (*In re Lamictal*, No. 14-1243.) In November 2016, the Supreme Court declined to hear the defendants' appeal of the Third Circuit's ruling. (*King Drug Co of Florence, Inc v SmithKline Beecham Corp*, 791 F3d 388 (3d Cir 26 June 2015)), cert denied, 137 S Ct 446 (2016).

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

Except in the case of a per se unlawful agreement between competitors (eg, price fixing or market allocation), courts evaluating antitrust claims typically place significant weight on a defendant's pro-competitive justifications for its conduct. Thus, conduct that increases the safety or efficacy of drugs, or makes it easier for patients to comply with drug regimens, is likely to be viewed favourably by the Antitrust Agencies and courts. Such justifications, however, will be weighed against possible anticompetitive effects and the existence of less restrictive alternatives. Additionally, when analysing antitrust issues, US courts keep in mind the regulated nature of the pharmaceutical sector and the economic importance of patent protection and generic substitution.

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

Not applicable.

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