Pharmaceutical Antitrust

Contributing editors
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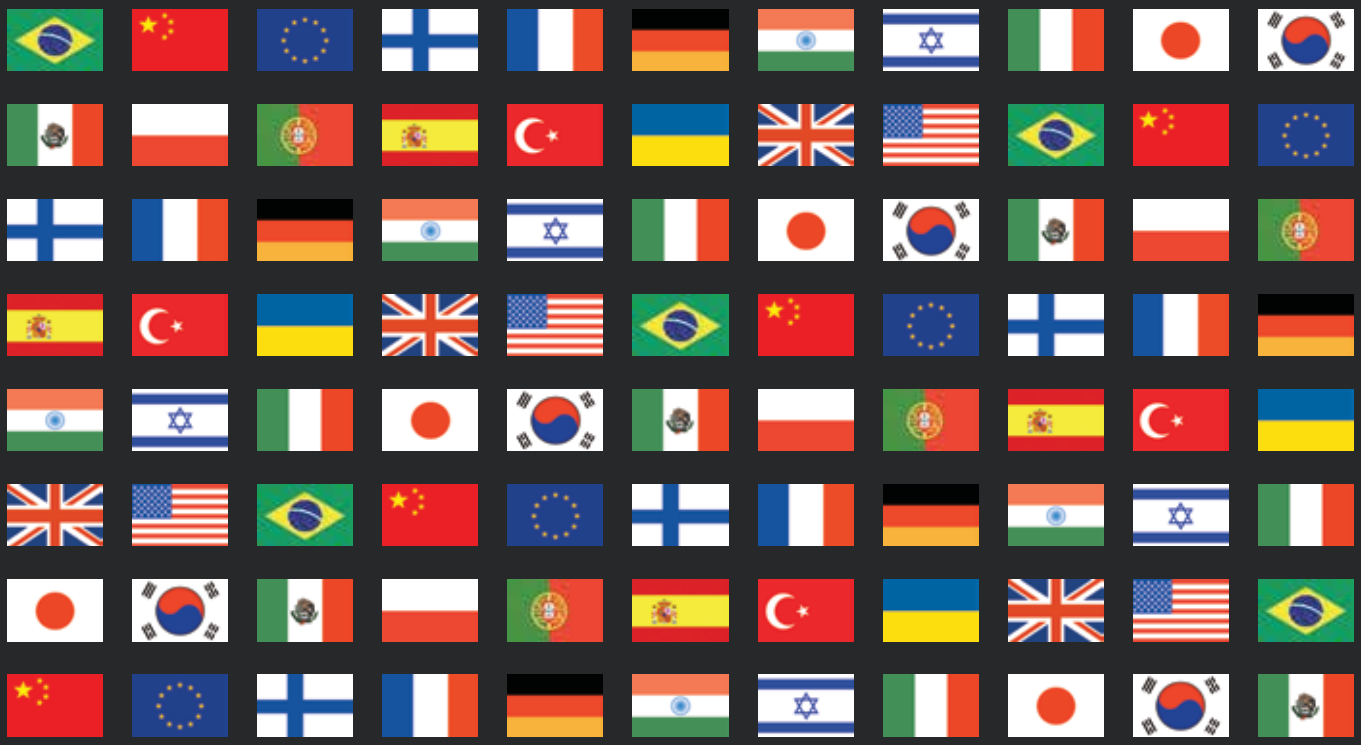

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GETTING THE DEAL THROUGH

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Pharmaceutical Antitrust 2017

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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
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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.

Israel

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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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