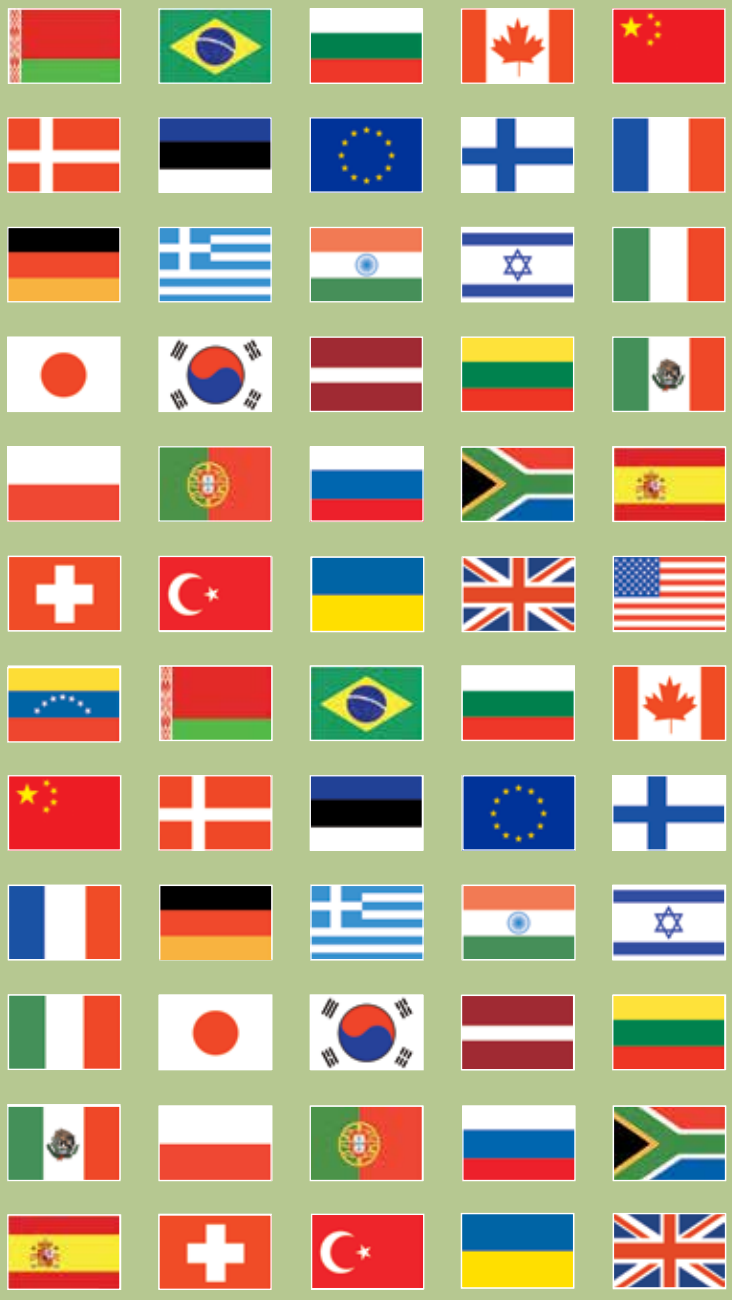
GETTING THE DEAL THROUGH

Pharmaceutical Antitrust

in 31 jurisdictions worldwide

2014

Contributing editor: Marleen Van Kerckhove



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Pharmaceutical Antitrust 2014

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Getting the Deal Through is delighted to publish the fully revised and updated seventh edition of *Pharmaceutical Antitrust*, a volume in our series of annual reports, which provide international analysis in key areas of law and policy for corporate counsel, cross-border legal practitioners and business people.

Following the format adopted throughout the series, the same key questions are answered by leading practitioners in each of the 31 jurisdictions featured. New jurisdictions this year include Israel, Poland and Spain.

Every effort has been made to ensure that matters of concern to readers are covered. However, specific legal advice should always be sought from experienced local advisers. *Getting the Deal Through* publications are updated annually in print. Please ensure you are always referring to the latest print edition or to the online version at www.GettingTheDealThrough.com.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. Getting the Deal Through would also like to extend special thanks to contributing editor Marleen Van Kerckhove at Arnold & Porter LLP for her continued assistance with this volume.

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Publisher
Gideon Roberton
gideon.roberton@lbresearch.com

Subscriptions
Rachel Nurse
subscriptions@gettingthedealthrough.com

Business development managers
George Ingledew
george.ingledew@lbresearch.com

Alan Lee
alan.lee@lbresearch.com

Dan White
dan.white@lbresearch.com

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Israel

David E Tadmor, Shai Bakal and Ido Cnaan

Tadmor & Co Attorneys at Law

Pharmaceutical regulatory law

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

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. Cosmetic products, food products and medical equipment are governed by different regulation.

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.

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 (OTC drugs). The sale of OTC drugs is regulated by the Pharmacist Regulations (the sale of non-prescription preparation 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 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 Price Supervisor 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.

Another relevant piece of legislation is the Patents Law, 5727-1967, 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.

2 Which bodies are entrusted with enforcing these regulatory rules?

The registration and authorisation of pharmaceutical products is managed by the MoH, which is empowered, among other things, to regulate the marketing and manufacturing of pharmaceutical products for both innovator and generic drugs. The main purpose of such regulation is to ensure that each drug meets high standards of quality, effectiveness and safety. The MoH is also a customer of pharmaceutical products, since it is the owner of several governmental hospitals and it grants subsidies to other, non-governmental health institutions. Therefore, the MoH has a vested interest in promoting competition in the sale of pharmaceutical products in Israel.

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 which 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 concentration and limited 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 three types of restraints on trade: restrictive arrangements, merger transactions and abuse of dominant position.

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).

The Antitrust Law was recently amended, granting the Commissioner new powers to regulate oligopolistic markets. Among these powers is the authority to issue directives with the aim of increasing competition in markets characterised by high concentration and a tendency towards parallel behaviour.

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

There are no guidelines specific to the pharmaceutical sector, although general guidelines may be applicable to the pharmaceutical sector as well (eg, the Guidelines for Competitive Analysis of Horizontal Mergers (the Horizontal Mergers Guidelines)).

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

The government agency responsible for the implementation and enforcement of the Antitrust Law is the Israeli Antitrust Authority (IAA).

7 What remedies can competition authorities impose for anti-competitive 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:

- A declaration of breach – 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 – 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 a rather recent amendment to the Antitrust Law, in certain oligopoly markets, the Commissioner may declare the oligopoly members as a 'Concerted Group' and issue directives aimed at preventing harm to competition or increasing competition.
- Monetary payments – According to a recent amendment to the Antitrust Law, 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 million New Israeli shekels for individuals and up to 24 million New Israeli shekels on corporations.

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

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 Israeli 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 Israeli 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 anti-competitive 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.

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

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 (the Competition Division) was formed. The Competition Division is responsible for conducting sector-wide inquiries. However, such inquiries are still in their infancy.

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

The enforcement of competition regulation is vested with the Commissioner. The MoH's broad powers over the pharmaceutical sector may be exercised in a way that will deeply effect competition. In these instances, or when an IAA decision is expected to materially affect the MoH regulation, a dialogue between the IAA and the MoH is likely to precede any decision made by each regulator.

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

The Antitrust Commissioner's decisions are normally based solely on the interest of competition. Industrial policy arguments may be relevant inasmuch as they relate to efficiency justifications. In the area of restrictive arrangements, the Antitrust Tribunal is authorised to approve a restrictive arrangement based on industrial policy and other, non-competitive, considerations.

12 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 consumers 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

13 To what extent are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

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, due to 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. This was the IAA's practice, for instance in the *Schering-Plough/Merck* merger (approval granted after five months, immediately after the transaction was approved by the FTC).

14 How are product markets 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 (SSNIP test)). As a practical indication, the IAA will use an increase of between 5 and 10 per cent for a period of one year.

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. 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 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.

15 In what circumstances will a product and geographical overlap between two merging parties 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.

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

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 how big the potential market for the developed product is.

17 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, out of 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 if and what sort of remedies are suitable in a particular case is based on the specific circumstances. However, the guidelines state the general preference for structural remedies (such as the divestment of overlapping business) on 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 mix 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 enters into a licensing agreement with an independent third party for the distribution 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.

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

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.

Anti-competitive agreements

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

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. The definition of restrictive arrangement was given a broad meaning, so that almost any form of collaboration between competitors, as well as many vertical agreements, 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, intra-group 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 anti-competitive 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.

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

As mentioned above, the Antitrust Law imposes criminal liability for any violation of the Antitrust Law. The IAA will normally use criminal enforcement for hard-core cartel offences, bid rigging and other gross violations of the Antitrust Law. The pharmaceutical sector is no exception. A criminal investigation entails serious ramifications. The IAA usually seizes a vast amount of corporate documents, and detains corporate management for questioning (in certain cases, arrests are made).

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

There are no particular guidelines regarding technology licensing agreements. The statutory exemption set in article 3(2) of the Antitrust Law exempts restrictions relating to the licensing of certain IP rights (such as patents, trademarks, copyrights etc), 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.

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

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.

23 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 is, 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 apposed 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 is likely to reduce competition in what he described as very concentrated markets.

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

Typically, vertical price restrictions (especially minimum or fixed retail price maintenance (RPM)) and exclusivity agreements are at the centre of attention. Parameters that are relevant to the assessment of such agreements include: 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.

25 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.

Anti-competitive unilateral conduct

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

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 27), 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 anti-competitive 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), is subdivided into two subcategories:
  - 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.

27 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 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.

Update and trends

The costs of the Israeli health system have been at the heart of public focus in recent years. This attention, along with the recent trend of privatisation in the health system, has led to increased involvement of the relevant regulators (ie, the IAA and Health Ministry) when examining and formulating reforms that are meant to improve the system's efficiency and increase competition.

28 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 or not will be made in accordance with his or her position in the market, and will not be affected by the mere holding of a patent.

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

The mere exercising of a patent right within the grant of a patent or the mere attempt to register a patent will normally not be deemed an abuse of a dominant position. Nonetheless, a sham application for patent or an abuse of the patent beyond its statutory scope may be considered an abuse of a dominant position.

In the *Magal* case (Antitrust 3/97 *Magal v General Director of IAA*), the Antitrust Tribunal held that even when the patent de facto yields a monopoly position, this does not necessarily grant its owner carte blanche to abuse its market position in contravention of the Antitrust Law.

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

As long as the enforcement of the patents is done within the grant of the patent, it is generally not considered an antitrust violation.

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

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.

32 Do authorised generics raise issues under the competition law?

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.

33 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. Efficacy and the 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.

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

There has been no evident increase in the IAA's enforcement in the sector.

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

The area of follow-on litigation in the pharmaceutical industry is undeveloped, given the limited public enforcement in this sector.

Tadmor & Co Attorneys at Law

David E Tadmor **david@tadmor.com**
Shai Bakal **shai@tadmor.com**
Ido Cnaan **ido@tadmor.com**

132 Menachem Begin Road
5 Azrieli Center Square Tower, 34th Floor
Tel Aviv 6701101
Israel

Tel: +972 3 684 6000
Fax: +972 3 684 6001
www.tadmor.com

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