Pharmaceutical Antitrust

Contributing editors
Marta Giner Asins and Yann Anselin

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GETTING THE DEAL THROUGH

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Norton Rose Fulbright LLP

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Preface

Pharmaceutical Antitrust 2018

Eleventh edition

Getting the Deal Through is delighted to publish the eleventh 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. Our coverage this year includes new chapters on Bulgaria, Canada and Romania.

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

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Canada

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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?

Pharmaceutical products are regulated under the Food and Drugs Act and associated regulations. To be marketed in Canada, drug products require pre-market approval in the form of a drug identification number. Additionally, new drugs require a notice of compliance (NOC). Innovative pharmaceutical companies obtain an NOC by submitting a new drug submission (NDS) that contains data on the safety and effectiveness of the new product to Health Canada. Generic manufacturers can also apply via the NDS pathway, or they can file an abbreviated new drug submission that demonstrates bioequivalence to a marketed Canadian reference product. If a generic company references a medication with a patent listed on the Patent Register, the Patented Medicines (Notice of Compliance) Regulations provide a framework that allows the generic to allege patent invalidity or non-infringement before receiving its NOC. Alternatively, the generic can agree to await patent expiry before receiving approval of its product.

The Food and Drugs Act and Food and Drug Regulations also govern marketing of pharmaceutical products. Advertising of prescription products to the general public is prohibited except in respect of name, price and quantity. Advertising of prescription drugs to healthcare professionals (HCPs) is permitted, as is advertising of non-prescription drugs; however, in all cases, it must not be misleading, deceptive or likely to create an erroneous impression. What this means is largely determined by industry organisations.

The Pharmaceutical Advertising Advisory Board has a Code of Advertising Acceptance and pre-clears advertising copy for prescription pharmaceutical products. Innovative Medicines Canada and Biotech Canada have codes of ethical practices that govern marketing activities of member companies. For non-member companies, these codes represent industry best practices. Likewise, generic manufacturers adhere to the Canadian Generic Pharmaceutical Association's Code of Marketing Conduct Governing the Sale of Generic Pharmaceutical Products in Canada. Advertising Standards Canada has a Canadian Code of Advertising Standards that applies to any direct-to-consumer advertising of non-prescription products. Enforcement of advertising generally falls to these organisations. However, in certain cases such as where there is a potential health risk, wilful non-compliance, direct-to-consumer advertising of a prescription drug or marketing of an unauthorised product, Health Canada will review complaints and impose penalties where appropriate.

Pricing of prescription products is regulated by the Patented Medicine Prices Review Board (PMPRB). Under the Patented Medicines Regulations made under the Patent Act, the PMPRB has jurisdiction for any product to which a patent 'pertains' and it takes a broad view of what pertains. If no patents pertain, then the price is unregulated. Additionally, public and private payers can impose pricing restrictions on products that they elect to provide coverage for on provincial and private formularies. There are significant price restrictions imposed on generic products in Canada, with some being limited to 10 per cent of the price of the equivalent brand product.

As discussed further below, the Competition Act (the Act) also contains provisions that apply to pharmaceuticals. If the drug product is a narcotic or controlled substance, the Controlled Drugs and Substances Act and associated regulations contain other provisions.

2 Are drug prices subject to regulatory control?

As discussed above, drug prices are subject to regulatory control as long as a patent pertains. The PMPRB considers several factors when determining an appropriate price for a patented medication. These include the level of therapeutic improvement over other products, prices of products in the same therapeutic class and prices charged in certain other countries. Annual price increases are evaluated in reference to the consumer price index.

At the time of writing, there are proposed changes to the Patented Medicines Regulations that will impact the factors considered. These changes may include a change to reference comparator countries (effectively lowering the comparator prices) and the introduction of three new pricing factors: a pharmacoeconomic evaluation, the size of the market and gross domestic product. The proposed regulations also increase reporting requirements.

Generic prices are further controlled by public payers. For example, in Canada's largest province, Ontario, the Ontario Drug Benefit Act and associated regulations limit the price charged by generic companies for any drug covered under the provincial plan. Public payers have also begun negotiating as a group under the pan-Canadian Pharmaceutical Alliance, which also places limits on the acceptable prices charged by generic manufacturers. Generic products are priced at between 10 and 75 per cent of the innovator product's price, depending on the number of generics on the market and the molecule itself. These limitations apply as long as a drug is listed.

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

The distribution of pharmaceutical products is regulated at both the federal and provincial levels. Federal regulations, including the Food and Drug Regulations, impose limits and licensing obligations on those who fabricate, package or label, test, import, distribute and wholesale.

Wholesaling may be further regulated at the provincial level (eg, in Ontario, wholesalers must register with the Ontario College of Pharmacists). All provinces regulate HCPs. Generally speaking, prescription drugs must be sold by a regulated HCP (generally a pharmacist, although others are allowed to distribute to varying degrees, depending on the province). Some provinces also impose regulations on the ability of manufacturers and wholesalers to pay rebates to pharmacies.

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

Competition between innovative drug manufacturers and generic manufacturers is significantly affected by the PMPRB, the regulation of provincial formularies (ie, reimbursement regimes) and the regulations governing marketing authorisations. Additionally, the various codes, referenced in question 1, that deal with the nature of claims that can be made in advertisements and other marketing materials are also important.

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Competition legislation and regulation

5 Which legislation sets out competition law?

The Act sets out Canada's competition law.

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

The Canadian Competition Bureau (the Bureau) administers and enforces the Act, including reviewing pharmaceutical mergers and investigating anticompetitive activities in the pharmaceutical sector.

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

The Act covers two broad tracks, being criminal and civil remedies, for anticompetitive conduct or agreements between competitors such as pharmaceutical companies.

Section 45 creates a per se criminal offence for cartel-type conspiracy agreements between competitors, while section 90.1 creates a civil remedy that allows the Commissioner of Competition (the Commissioner) to challenge agreements that are not within the scope of a section 45 offence but that may prevent or lessen competition substantially.

Criminal charges can be laid against individuals and corporations under section 45 for conspiring to fix prices, allocate markets or restrict supply, and the penalty can be a fine of up to C$25 million or up to 14 years of imprisonment, or both.

Under section 90.1, the Commissioner can bring an application to the Competition Tribunal (the Tribunal). The only available remedy is the issuance, by the Tribunal, of an order that prohibits the offending conduct or that requires the person to take some action, or both.

Other anticompetitive conduct is also prohibited under the Act, including:

- abuse of dominant position (the Tribunal can make an order prohibiting the offending conduct and imposing an administrative monetary penalty of up to C$10 million for a first order);
- refusal to deal (the Tribunal can make an order requiring that the supplier accept a customer);
- price maintenance (the Tribunal can make an order prohibiting the offending conduct); and
- exclusive dealing, tied selling and market restrictions (the Tribunal can make an order prohibiting the offending conduct).

8 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?

There are two possible avenues for private parties to obtain competition-related remedies.

The first is section 36 of the Act, which creates a private right of action for persons that have suffered a loss or damage as a result of conduct contrary to the criminal provisions of the Act or breach of a civil prohibition order. The affected person can seek to recover damages from the person who engaged in the conduct in an amount equal to the loss or damage proved. Most proceedings under section 36 are class actions, where an applicant claims damages for losses resulting from price fixing, etc.

The second avenue allows a person to apply to the Tribunal for leave, under section 103.1 in respect of refusals to deal, price maintenance, exclusive dealing, tied selling and market restrictions. However, remedies available under this process are limited to prohibition orders, and monetary damages are expressly not available.

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?

The Bureau conducts sector-wide inquiries from time to time, although the Act provides no explicit legislative basis to do so. The Bureau will often pick an area of focus, which could be the result of information it learned during a merger filing, through a complaint or of its own initiative.

The Bureau has undertaken a number of studies of the pharmaceutical area, including a 2007 study on the generic drug sector, hosting a one-day symposium on competition issues in the pharmaceutical industry in 2013, and releasing a white paper in September 2014 on patent litigation settlement agreements. The Bureau also made a submission to the OECD Competition Committee roundtable on Competition Issues in the Distribution of Pharmaceuticals in 2014. All of these are available on the Bureau's website.

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

The Bureau does consult NGOs, trade associations or consumer groups when reviewing mergers and as part of inquiries into both civil and criminal matters. While these groups could bring private litigation, they rarely do so. These entities can also play a role in bringing allegations of anticompetitive conduct to the attention of the Bureau through a variety of means.

Review of mergers

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

Yes, specific features of the pharmaceutical industry will be taken into account when the Bureau is assessing a merger between two pharmaceutical companies. For instance, the regulatory regime in which pharmaceutical companies in Canada operate will be an important consideration in assessing a merger (eg, as this relates to barriers to entry).

In the Bureau's position statement on Teva Pharmaceuticals Industries Ltd's (Teva) proposed acquisition of Allergan plc's generic pharmaceutical business in 2016, it stated that it assessed the regulatory framework in Canada with respect to the development of new generic drugs. In particular, the Bureau examined certain public and non-public information on drugs currently under development, and coordinated with Health Canada to make assessments as to the expected timing for regulatory approval and entry into the market.

In a 2017 merger concerning retail pharmacies in the province of Quebec, the Bureau took into account the regulation of pharmacists and prices of generic drugs in Quebec to conclude that the transaction did not substantially lessen competition.

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

As stated in the Bureau's Merger Enforcement Guidelines (MEGs), for the purpose of product market definition, what matters is not the identity of sellers, but the characteristics of the products and buyers' ability or willingness to switch from one product to another in response to changes in relative prices. A relevant product market consists of a given product of the merging parties and all substitutes required for a small but significant and non-transitory increase in price (SSNIP) to be profitable.

In determining the relevant product market for a merger in the pharmaceutical sector, the Bureau will typically seek detailed information on products currently supplied by the merging parties in Canada in an effort to assess any competitive overlaps. Given the sophistication of the pharmaceutical sector, parties may need to disclose information not only on a product category level, but also on a product molecular basis.

For example, in respect of the generic pharmaceutical industry, the Bureau will typically find that the parties' products will generally be considered within the same relevant product market where they contain the same molecule or active ingredient and are supplied in the same format.

For the purpose of geographic market definition, the Bureau will assess buyers' ability or willingness to switch their purchases in sufficient quantity from suppliers in one location to suppliers in another, in response to changes in relative prices. A relevant geographic market consists of all supply points that would have to be included for an SSNIP to be profitable.

The relevant geographic market for the supply of pharmaceutical products is typically defined to be no broader than Canada, as significant regulatory barriers limit the entry of pharmaceutical products from outside of Canada.

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Owing to provincial regulation of healthcare, pharmacies and the pricing of generic drugs, the relevant geographic market is often provincial in scope.

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

Yes, as stated in the MEGs, when considering cost savings brought about by a proposed merger in relation to the efficiency defence under section 96 of the Act, the Bureau examines claims related to, among other things, savings that arise from the rationalisation of research and development activities.

Additionally, the Bureau also examines claims that the merger has, or is likely to result in, gains in dynamic efficiency, including those attained through the optimal introduction of new products, the development of more efficient productive processes and the improvement of product quality and service.

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

A proposed merger that will result in a post-merger market share of 35 per cent or greater will typically garner heightened scrutiny by the Bureau. Mergers that give rise to market shares that exceed this threshold are not, however, necessarily deemed anticompetitive by the Bureau. Under these circumstances, the Bureau examines various factors to determine whether such mergers would likely create, maintain or enhance market power, and thereby prevent or lessen competition substantially.

For example, in April 2016, the Bureau found that Teva's proposed acquisition of Allergan plc's generic pharmaceutical business would likely have resulted in a substantial lessening or prevention of competition for the sale of two pharmaceutical products in Canada (tobramycin inhalation solution and buprenorphine/naloxone tablets) owing to the elimination of future competition between the parties.

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

Overlaps with respect to products under development will, in all probability, be considered problematic under the merger provisions of the Act where the products are likely to receive regulatory approval, the products will be sold in Canada within a reasonable period of time following the merger and the post-closing merged company will be able to exercise market power in respect of the products.

By way of an example, pursuant to the terms of a consent agreement the Bureau entered into with Merck & Co, Inc and Schering-Plough Corporation in relation to their proposed merger, the parties agreed to divest to a third party a human health product that was currently under development for the treatment of chemotherapy-induced and post-operative side effects. This divestiture was designed to protect future competition for the supply of products used in the treatment of these medical conditions.

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

Typical remedies required in the case of anticompetitive mergers involve the divestitures of assets (ie, structural remedies).

For example, the remedy imposed by the Bureau in Teva's 2016 acquisition of Allergan's generic pharmaceutical business (see question 11) involved Teva entering into a registered consent agreement with the Bureau, the terms of which require Teva to divest either its own or Allergan's Canadian assets relating to tobramycin inhalation solution and buprenorphine/naloxone tablets to buyers approved by the Commissioner.

Additionally, in December 2016, the Bureau entered into a consent agreement with McKesson Canada Corporation to resolve concerns related to its proposed acquisition of the healthcare businesses of the Katz Group, which include the Rexall pharmacy retail chain and the ClaimSecure healthcare claims adjudication business. This consent agreement required McKesson to sell retail chain locations in 26 markets. It further restricted McKesson from transmitting commercially sensitive information between its pharmaceutical wholesale business and the Rexall retail business, to ensure that competition is preserved for the wholesale and retail supply of pharmaceutical products and services in local markets across Canada.

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

Pursuant to sections 109 and 110 of the Act, the acquisition of assets in Canada would be subject to merger reporting requirements if the 'party-size' threshold and the 'transaction-size' threshold are exceeded.

The party-size threshold is exceeded where the parties to the transaction, together with their affiliates, have assets in Canada that exceed C$400 million, or gross revenues from sales in, from or into Canada, that exceed C$400 million.

The transaction-size threshold is exceeded where the aggregate value of the acquired assets or the gross revenues from sales in or from Canada generated from those assets, would exceed C$92 million.

Thus, if the purchaser and the seller exceed the party-size threshold, and the patents and licences being sold had a book value, or generated revenues, that exceeded the transaction-size threshold, the transaction would be subject to the merger reporting requirements of the Act.

Anticompetitive agreements

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

Offences in relation to competition are set out in Parts VI and VII of the Act. Section 45 makes it an offence to:

- conspire, agree or arrange with a competitor to fix, maintain, increase or control the price for the supply of a product;
- to allocate sales, territories, customers or markets for the production or supply of a product; or
- to fix, maintain, control, prevent, lessen or eliminate the production or supply of a product.

Where these conditions are not met, an agreement may nonetheless be reviewable under section 90.1 of the Act where it prevents or lessens, or is likely to prevent or lessen, competition substantially in a market.

Additionally, agreements involving abuses of dominance may be reviewed under section 79 of the Act, which allows the Tribunal, on application by the Commissioner, to make an order prohibiting persons that substantially or completely control a class of business from engaging in practices of anticompetitive acts that have had, are having or are likely to have, the effect of preventing or lessening competition substantially in a market. However, note that subsection 79(5) of the Act sets out that an act engaged in, pursuant only to the exercise or enjoyment of any interest derived under certain IP legislation including the Patent Act, is not an anticompetitive effect for the purposes of the abuse of dominance provision.

With respect to IP specifically, in its Intellectual Property Enforcement Guidelines (IPEGs), the Bureau sets out its framework for approaching anticompetitive conduct associated with the exercise of IP rights. The Bureau sets out that the Act generally applies to conduct involving IP as it would apply to conduct involving other forms of property. However, the Bureau applies a two-pronged approach to cases involving IP or IP rights: those involving something more than the mere exercise of the IP right; and those involving the mere exercise of the IP right and nothing else. The Bureau states in the IPEGs that it will use the general provisions of the Act (including those discussed above) to address the former circumstances and section 32 (special remedies) to address the latter. Section 32 addresses situations involving the use of exclusive rights and privileges conferred by patents, trademarks or copyrights to, for example, restrain trade or limit the production of products. In such cases, the Federal Court may take action, including declaring such an agreement or licence void in whole or in part. With respect to the general provisions, in practice, the mere exercise of IP rights has not been found to offend the Act.

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19 To what extent are technology licensing agreements considered anticompetitive?

According to the IPEGs, licensing is, in many cases, pro-competitive, in that it facilitates use of an IP right by additional parties. However, in order to assess whether a technology licensing agreement is anti-competitive, the Bureau would examine the terms of the licence and assess whether they create, enhance or maintain the market power of either party to the agreement. Generally, the Bureau will 'not consider licensing agreements involving IP to be anticompetitive unless they reduce competition substantially relative to that which would have likely existed in the absence of the licence's potentially anticompetitive terms'.

Several cases have dealt with IP licensing agreements. For example, in *Canada (Director of Investigation and Research) v Tele-Direct (Publications) Inc*, the Tribunal found that the enforcement of trademark rights, including the refusal to license trademarks, even selectively, were not anticompetitive acts within the meaning of section 79(5) of the Act, because the Trademark Act grants to trademark owners the right to exercise these very rights.

The recent case of *the Commissioner of Competition v the Toronto Real Estate Board* (TREB), 2016 Competition Tribunal 7, also dealt in part with IP licences. The case involved a restriction on certain virtual uses of the TREB real estate multiple listing service (MLS) database. TREB argued that its copyright in the MLS database was a complete defence to the allegations that it had abused its dominance contrary to section 79 of the Act. In its 2016 decision, the Tribunal found, among other things, that the restrictions were more than the 'mere exercise' of TREB's IP rights. TREB also argued that the Tribunal did not have jurisdiction to order it to grant compulsory IP licences, but the Tribunal found that its broad remedial jurisdiction included jurisdiction in respect of IP rights. In December 2017, the Federal Court of Appeal dismissed TREB's appeal with costs (see *Toronto Real Estate Board v the Commissioner of Competition*, 2017 FCA 236). TREB recently announced it would seek leave to appeal to the Supreme Court of Canada.

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

Such agreements are not per se or typically considered anticompetitive and are on their own unlikely to infringe the Act, particularly if the parties to the agreement are not competitors. However, the agreement may be considered an offence under section 45 if the parties to the agreement are competitors and the agreement, for example, fixes the price for the supply of a product, allocates sales territories or controls the production or supply of a product. Alternatively, the agreement may be reviewable under section 90.1 if the co-promotion or co-marketing agreement prevents or lessens, or is likely to prevent or lessen, competition substantially in a market.

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

Any type of agreement, whether existing or proposed, between persons, of whom two or more are competitors, that prevents or lessens, or is likely to prevent or lessen, competition substantially in a market is reviewable under section 90.1. This provision could capture all types of agreements, including supply and distribution agreements, joint ventures, collaborative research agreements and consortium agreements.

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

There is no definition of 'vertical restraint' in the Act; however, the Act sets out various types of vertical restraints that are reviewable under Part VIII, including:

- tied selling: where a supplier, as a condition of supplying a particular product, requires or induces a customer to buy another product or other products;
- refusal to deal: where, under certain circumstances, a business refuses to supply a product to another business despite that business being willing and able to meet the supplier's usual trade terms;
- exclusive dealing: where a supplier requires or induces a customer to deal only, or mostly, in certain products;
- resale price maintenance: when a supplier prevents a customer from selling a product below a minimum price by means of a threat, promise or agreement, or where a supplier refuses to supply a customer because of their low pricing policy;
- market restrictions: where the supplier requires the customer to sell the specified products in a defined market (ie, by penalising the customer for selling outside that defined market);
- abuse of dominance: when a dominant firm, or group of firms, in a market engages in conduct intended to eliminate or discipline a competitor or to deter future entry by new competitors, with the result that competition is prevented or lessened substantially;
- delivered pricing: the practice of refusing a customer, or potential customer, delivery of an article at any place where the supplier delivers the article to any other of the supplier's customers, on the same trade terms; and
- foreign refusal to supply: where a supplier outside Canada has refused to supply or otherwise discriminated in the supply of a product to a person in Canada at the instance and by reason of the exertion of buying power outside Canada by another person.

These restrictions are found in sections 75 to 81, and 84 of the Act.

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

According to the Bureau's IPEGs, an 'entry–split' settlement, pursuant to which generic firms enter the market on or before patent expiry, will not pose an issue under the Act. In other words, the Bureau is generally not concerned with settlements that specify a market entry date for a generic company that is on or before the expiry date of the patent and in which the generic company does not receive any other consideration.

However, a settlement pursuant to which the generic company enters the market on or before patent expiry and that includes a payment to the generic company, may be reviewed under section 90.1 of the Act or, in cases involving a potential abuse of dominance, section 79.

The Bureau will generally not review a settlement under section 45 unless it is a 'sham' or it extends beyond the exclusionary potential of the patent by delaying generic entry past the date of patent expiry or by restricting competition for products unrelated to the patent in question. For further information, see section 7.3 of the Bureau's IPEGs.

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

Competitors are not, per se, prohibited from engaging in joint communications or lobbying, but should exercise caution when doing so. The Bureau publishes a pamphlet that includes dos and don'ts for trade associations and their members. Among other things, trade associations and their members should:

- use a third party to collect and disseminate information;
- disseminate information in aggregated form;
- ensure that measures are in place to prevent the disclosure of competitively sensitive information to or between individual association members; and
- discourage private meetings between competitors under the pretext of association meetings.

Trade associations should not:

- coerce members into sharing information or data (either directly or through use of unreasonable disciplinary measures);
- set unreasonable or arbitrary criteria for membership such that certain competitors (or categories thereof) are excluded;
- discriminate or impose sanctions against firms that do not adhere to rules regarding competitively important considerations;
- engage in any form of price setting;
- restrict advertising; or
- use standard setting to artificially provide some competitors (actual or potential) with a competitive advantage over others.

Members of trade associations must of course refrain from communicating competitively sensitive information with one another, either at association meetings or related social events.

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25 To what extent may public communications constitute an infringement?

Generally, public communications will not constitute an infringement of competition law unless they, for example, constitute price signalling to competitors or they communicate planned market behaviours that could lead to coordinated actions by competitors within the market. If a public communication is made for the purposes of promoting a business interest and contains a statement that is false or misleading, that could pose issues under the misleading advertising provisions of the Act.

26 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?

Not necessarily, though competitors should be sure not to disclose competitively sensitive information to one another in the context of such disclosures, either directly or through intermediaries such as HCPs.

Anticompetitive unilateral conduct

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

In Canada, abuse of dominance is a civil reviewable matter, meaning that there is no liability until the Tribunal actually makes a finding that abuse of dominance has occurred. The provision is for general application to all sectors of the economy, a fact underscored by the 2009 repeal of special provisions designed to address abuse of dominance by a domestic airline and other sector-specific guidance that has been removed from the Enforcement Guidelines on the Abuse of Dominance Provisions (2012 Guidelines).

The Commissioner must prove three elements on a balance of probabilities before the Tribunal may make an order proscribing the behaviour or imposing an administrative monetary penalty:

- that one or more persons substantially or completely control, throughout Canada or any area thereof, a class or species of business;
- that the person or persons have engaged in or are engaging in a practice of anticompetitive acts; and
- that the practice has had, is having or is likely to have the effect of preventing or lessening competition substantially in a market.

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

The first element of abuse of dominance in Canada is that a firm or firms must have a dominant market position (ie, substantially or completely controlling a class or species of business). However, there is no minimum size of the market that must be controlled or affected to raise concerns.

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

As noted in question 27, there are three elements to the abuse of dominance provision, and holding market power is a key consideration. Canada's abuse of dominance law looks to market share as evidence of market power or dominance. A prima facie determination of market power may be made on the basis of market share in the relevant market. To date, there is no specific market share threshold for prima facie market power. All of the contested abuse cases thus far have concerned market shares in excess of 80 per cent, where a prima facie case was relatively obvious. But Canadian cases have found that 'no prima facie finding of dominance would arise' with respect to a market share below 50 per cent, and a 25 per cent market share 'falls well short of a level that might be considered to indicate market power'.

Notwithstanding these pronouncements by the Tribunal, from an enforcement perspective, the 2012 Guidelines state that the Bureau's general approach (to market share) is as follows:

- a market share of less than 35 per cent will generally not prompt further examination;
- a market share of between 35 and 50 per cent will generally only prompt further examination if it appears the firm is likely to increase its market share through the alleged anticompetitive conduct within a reasonable period of time;
- a market share of 50 per cent or more will generally prompt further examination; and
- in the case of a group of firms alleged to be jointly dominant, a combined market share equal to or exceeding 65 per cent will generally prompt further examination.

It is important to note that the case law is clear that although market share is important to the abuse analysis, a finding of market power must be supported by findings other than market share, such as the existence of barriers to entry, the number and effectiveness of competitors, excess capacity and the state of the market.

Update and trends

After closely studying the industry in 2013 and 2014 in connection with updating the IPEGs, and issuing white papers on patent settlement agreements, the Bureau has lessened its focus somewhat on the pharmaceutical industry. However, the Commissioner and the Bureau remain focused on the connection between competition policy and innovation, and this encompasses the pharma sector. For example, the Commissioner has noted that in order to ensure the IPEGs remain current, the Bureau will review them annually. Also, in considering 'exercising its enforcement discretion', the Bureau will examine the extent to which a remedy may alter the incentives to engage in research and development.

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

Merely holding a patent does not confer dominance on its holder. If the product market were defined narrowly so as to include only the patented product, then the holder may be dominant in that market. However, as noted in question 27, more than mere dominance is required. There must be some practice of anticompetitive acts. A patent holder would not likely be considered to be anticompetitive, though, if it faced no competitors as a result of its patent monopoly.

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

If the application was made in good faith, there would be no exposure to liability for an antitrust violation in Canada. Where the conduct involves 'something more' than the mere exercise of patent rights, then the general provisions of the Act may apply.

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

The Bureau has noted that the abuse of dominance provisions are the provisions of the Act 'most likely to apply to product-switching conduct' because the conduct 'involves anticompetitive acts by a single dominant company designed to exclude competitors and to create, maintain, or enhance its market power' (paragraph 34 of the Bureau's submission to the OECD Competition Committee roundtable on Competition Issues in the Distribution of Pharmaceuticals, 28 February 2014).

The Bureau investigated product switching by Alcon Canada under the abuse of dominance provisions, but in the end declined to refer the matter to the Tribunal after Alcon Canada reintroduced the product it had initially withdrawn from the market.

33 Can communications or recommendations aimed at the public or HCPs trigger antitrust liability?

Advertising of prescription products to the general public is prohibited, except in respect of name, price and quantity. Advertising of prescription drugs to HCPs is permitted, as is advertising of non-prescription drugs; however, in all cases it must not be misleading, deceptive or likely to create an erroneous impression.

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34 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?

A patent holder may market or license its drug as an authorised generic, or allow a third party to do so, before the expiry of the patent protection and, absent any other conduct or agreement, this should not raise concerns. The Bureau has stated that it may analyse such conduct in the context of other potentially anticompetitive conduct, such as pay-for-delay settlements and brand switching strategies.

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

As noted in question 1, the laws and regulations regarding pharmaceuticals in Canada prohibit the off-label promotion of drug products by drug manufacturers. To the extent drugs are discussed off label, it is only permissible at the HCP level (ie, in academic journals, continuing education, meetings, prescribing, etc). If a patent claimed the off-label use, the patent holder could enforce its patent against anyone who 'infringes' that claim.

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

Predatory pricing occurs when a company deliberately sets prices below cost for long enough to eliminate, discipline or deter entry by a competitor. This involves an expectation that the company will be able to recoup its losses later, by raising prices again. Predatory pricing is an anticompetitive act under the abuse of dominance provisions, described in question 27.

Merely having high prices is not abusive – the other elements of abuse of dominance must also be present.

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

Canadian common law includes a notion of a regulated conduct defence, which is an interpretative tool to deal with how to apply one statute to conduct that is authorised or required by a federal, provincial or other law. In one case, a generic manufacturer challenged an assignment of patent rights as contrary to section 45 of the Act dealing with anticompetitive agreements. The Federal Court held that a patent assignment could not lessen competition. Although the Federal Court of Appeal disagreed and held that it is possible that the assignment of a patent right 'may, as a matter of law, unduly lessen competition', the case was ultimately decided on other grounds.

38 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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