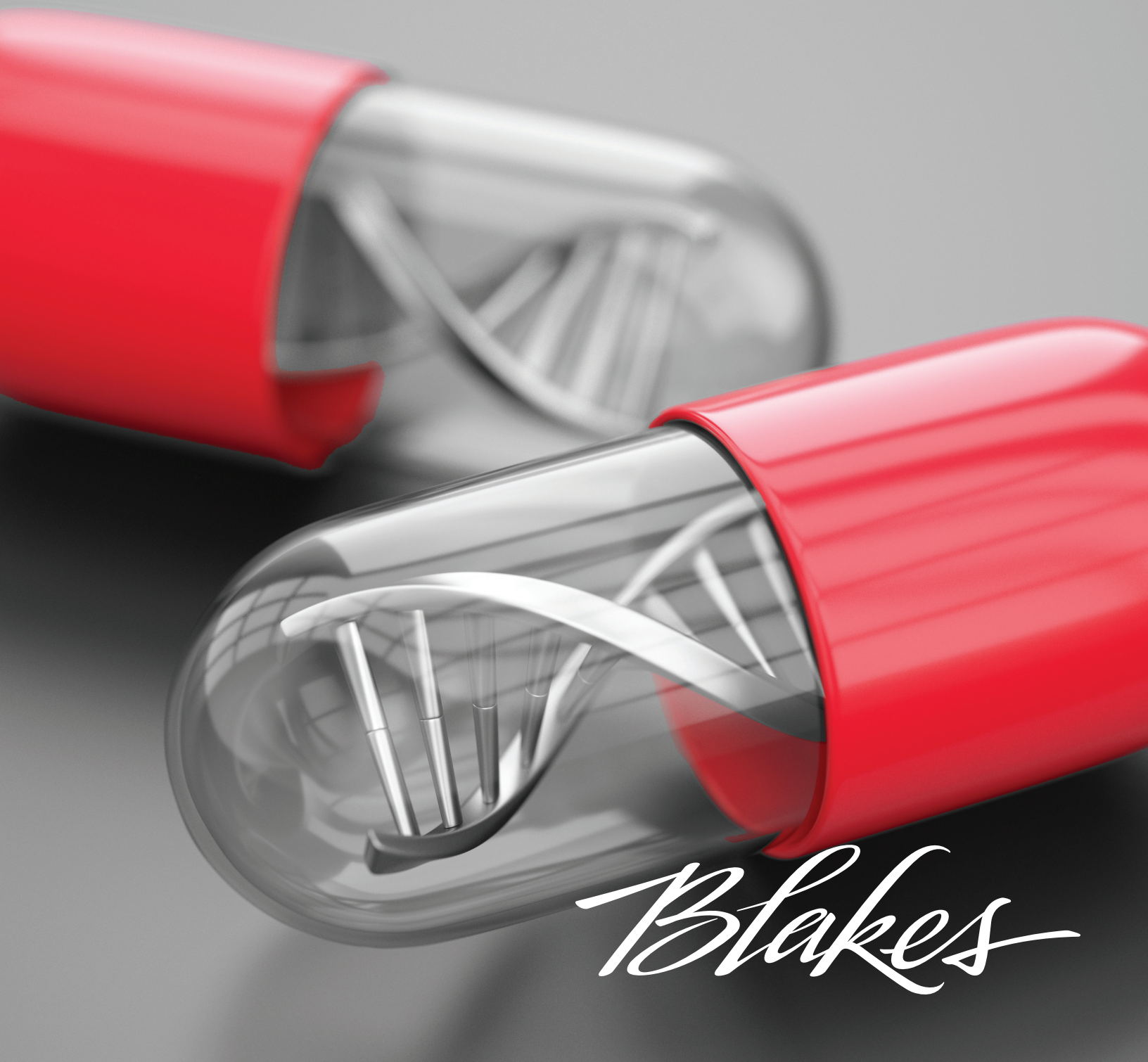
Pharmaceutical Industry

Competition Law in Canada



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Canada has a vibrant life sciences and pharmaceutical industry,

with a broad array of firms conducting research and developing innovative medicines, generic medicines, biosimilar products, consumer health-care products and medical devices.

These companies, which range from university-supported start-ups to multinational drug companies, are key to the commercialization of life sciences in Canada.

5 Things You Need to Know About the Pharmaceutical Industry and Competition Law in Canada

1. The Canadian Competition Bureau's interest in entry and expansion by producers of generics and biosimilars has motivated a number of recent investigations in the pharmaceutical industry.

2. The Commissioner of Competition has warned the pharmaceutical industry that any further alleged refusals to supply samples of brand name drugs to generic manufacturers will not be tolerated.

3. Competitors and customers are often a source of complaints for Canada's Competition Bureau.

4. Canada's Competition Bureau has recognized that competitor collaborations may be needed to supply critical products and services to Canadians in response to COVID-19.

5. Canada has a complex federal and provincial regulatory regime for pharmaceuticals that provides the context for the application of Canada's competition laws.

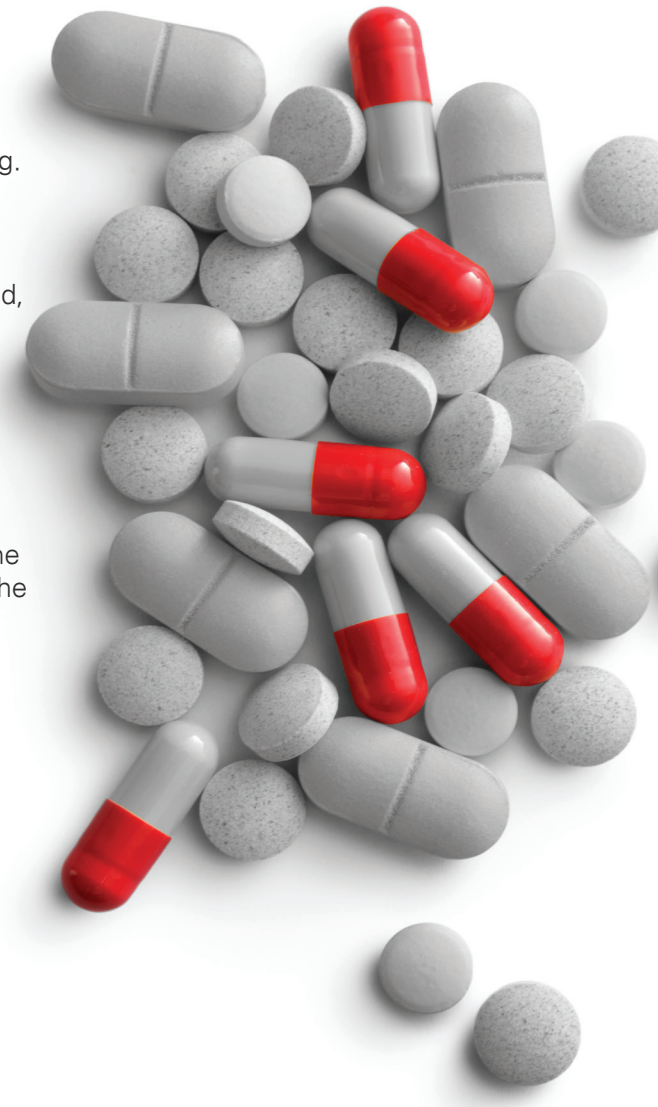
Competition Law Enforcement Framework

Like many developed economies, Canada has a competition law of general application called the *Competition Act* (Act). The purpose of the Act is, among other things, to "maintain and encourage competition in Canada in order to promote the efficiency and adaptability of the Canadian economy … and in order to provide consumers with competitive prices and product choices."

The Act contains numerous provisions potentially relevant to participants in Canada's pharmaceutical industry, including civil provisions relating to mergers and abuse of dominance and criminal prohibitions against certain types of agreements among competitors (cartels). However, the Act also includes important provisions that recognize intellectual property rights and the benefits of efficiency-enhancing behaviour.

The Act is administered and enforced by the Commissioner of Competition (Commissioner), the head of Canada's Competition Bureau (Bureau). The Act requires that mergers that exceed certain thresholds be reported to the Bureau for review — all reported and unreported mergers can be reviewed up to one year following closing. The Act also permits the Bureau to apply for court orders to produce data and documents, interview company executives and search property. However, the Bureau is not permitted to take action in respect of competitive conduct administratively or unilaterally. Instead, the Bureau may bring administrative proceedings to a specialized court, the Competition Tribunal (Tribunal), or refer criminal matters to the Public Prosecution Service of Canada (PPSC) for potential prosecution. Alternatively, the Bureau or PPSC may enter into settlements that resolve the Bureau's concerns.

The Bureau's recently released *Intellectual Property Enforcement Guidelines* address the Bureau's position when applying the Act in the health-care sector, including its treatment of product switching and the settlement of patent litigation proceedings.



Recent Trends in Enforcement

Practices in the pharmaceutical industry have been an area of periodic attention from the Bureau, with particular focus on ensuring that Canadians obtain the benefits of competition and innovation that come from this sector.

Recent trends in enforcement in the pharmaceutical industry in Canada include:

Activity in the Generic and Biosimilar Space

The Bureau has initiated a number of inquiries in the pharmaceutical industry related to alleged attempts to limit entry or expansion by the producers of generics or biosimilars. In particular, these inquiries have involved allegations that innovative pharmaceutical companies have engaged in various strategies to restrict entry and expansion by generic and biosimilar producers. The Bureau continues to express keen interest in bringing such cases to ensure Canadian consumers have access to generic and biosimilar medicines, and the Commissioner has warned the pharmaceutical industry that any further alleged refusals to supply samples of brand-name drugs to generic manufacturers will not be tolerated.

Competitor Collaborations Relating to COVID-19

Collaborations between competitors may be needed on an urgent basis to address issues arising from the COVID-19 pandemic. As a result, the Bureau issued a statement indicating it will generally refrain from exercising scrutiny in circumstances where there is a clear imperative for short-term collaboration to ensure the supply of products and services that are critical to Canadians in response to COVID-19, provided that any such collaboration is done in good faith and does not go any further than needed. The Bureau is also willing to provide an informal assessment of any proposed collaboration where parties believe that greater comfort is needed from the Bureau, which may be time limited as necessary to respond to the COVID-19 crisis.

More generally, competitor collaborations can potentially be structured to expedite any required or desired clearances or minimize issues under the Act, such as through a joint venture or other arrangement. Such civil competitor collaborations can be an important way for parties to enhance research and development efforts or achieve cost savings and other efficiencies absent a full-blown merger. When engaging in any such collaboration, effective management of communications between competitors, with the assistance of competition law counsel, can substantially reduce (and likely eliminate) the risk of criminal or civil contravention of the Act.

Policy Making

The Bureau has actively engaged in various studies of the pharmaceutical industry that resulted in reports that recommend changes to how drugs are regulated in Canada. The Bureau also recently updated its Intellectual Property Enforcement Guidelines. The update was largely (although not exclusively) for the purposes of describing how the Bureau intends to assess so-called "product hopping" and "reverse settlement" cases under the Act.

Public Advocacy

The Bureau occasionally advocates for changes to how different aspects of the health-care system are regulated. At different points in time, this advocacy has focused on regulation of pricing for generic medicines, regulation of professionals in the health-care industry and regulation of advertising in different health-care industries.

Non-Merger Business Practices

The Act contains numerous provisions regarding non-merger business practices that are potentially relevant to pharmaceutical industry participants. These include:

Criminal Offences for Price-Fixing and Bid-Rigging

It is a criminal offence to, among other things, enter into an agreement with a competitor or potential competitor to fix or control price or output; to allocate customers, markets, sales or territories; or to submit a bid (or refrain from submitting a bid) in response to a call for tender that was arrived at through an agreement with another person without providing notice of such agreement. These offences are punishable by significant fines and, for individuals, jail terms. Private parties can also sue for damages for violations of the criminal prohibitions, and these suits can be brought as class actions. Recent cases in Canada have significantly lowered the bar to class certification, and the damages sought are increasing.

For example, although there have been no reported cases, the Bureau's *Intellectual Property Enforcement Guidelines* note that litigation settlements between innovator and generic companies regarding disputes over patents may pose competition risks if the agreement of the parties goes beyond what is reasonably necessary to reach a settlement, such as including a payment to delay generic competition.

Civil Prohibitions on Abuse of Dominance

Business practices that constitute an abuse of dominance can be prohibited by the Competition Tribunal and may be subject to an administrative monetary penalty. Abuse of dominance occurs when a firm with market power engages in conduct that excludes or, otherwise, harms a competitor absent a legitimate business justification for the practice, and the practice prevents or lessens competition substantially. Any business practice that amounts only to the mere exercise of an intellectual property right is deemed not to be anti-competitive, but conduct that goes beyond the mere exercise of an intellectual property right could raise potential concerns if the requirements of the abuse of dominance provisions are satisfied. However, private parties cannot sue for damages for business practices that are alleged to be an abuse of dominance under the Act.

In the pharmaceutical sector, the Bureau has sought to apply the abuse of dominance provisions where it is alleged that a branded drug maker is trying to protect its market share for a medication that is losing patent protection in a practice known as "product hopping." For example, it may be alleged that an innovator company could withdraw a patented medication that is about to lose patent protection (Product A) from the market and introduce a slightly differentiated new patented medication (Product B) in its place. As a result, the allegation is that health-care professionals would switch to prescribe Product B to patients such that

new generic entrants would lose the sales from automatic substitutions by pharmacists of prescriptions for Product A. For instance, in 2004, the Bureau alleged that a branded drug maker withdrew an older product from the market and introduced a new replacement. However, this inquiry was discontinued after the initial product was reintroduced into the market.

Civil Competitor Collaborations

Agreements among competitors or potential competitors that prevent or lessen competition substantially can be prohibited by the Tribunal. Noother sanction (such as a fine) is available for such agreements. The Bureau has issued guidance explaining that it will use this provision to investigate agreements that do not rise to the level of "naked constraints," but that, nevertheless, have an anti-competitive effect. However, any agreement that results in efficiencies (including fixed-cost savings) that outweigh and offset the anti-competitive effects cannot be prohibited. In addition, private parties cannot sue for damages under the Act in respect of agreements that are not alleged to be criminal in nature.

Distribution Matters

The Act contains various provisions that permit the prohibition of different business practices relating to the distribution of products where those practices have different levels of anti-competitive effects. While private parties can seek the same orders, with leave of the Competition Tribunal, there are no sanctions (such as a fine) for these distribution practices, and private parties cannot sue for damages under the Act. Competition issues may arise where pharmaceutical suppliers wish to control the conditions under which distributors/retailers acquire or resell their products, including the prices at which products are resold (tied selling, exclusivity provisions, resale price maintenance).

Misleading Claims

The Act contains misleading advertising and deceptive-marketing practice restrictions. In particular, the Act prohibits making a representation to the public that is false or misleading in a material respect, where the representation is made to promote a product or business interest. If the false or misleading representation is made knowingly or recklessly, then it may contravene the criminal provisions of the Act.

Of particular relevance to the health-care industry are provisions that require any efficacy or performance claims to be based on a proper and adequate test.

Merger Review

Canada's framework for merger review has similarities to other jurisdictions and contains the following unique elements:

Notification Thresholds

The Act establishes various thresholds that, if exceeded, require that merging parties notify the Bureau of their transaction. The financial thresholds test the book value of the merging parties' assets and revenues in Canada. Typically, large pharmaceutical industry mergers (such as those between established firms) exceed these thresholds. Acquisitions of start-up companies (which typically do not have significant assets or revenues) are rarely subject to notification. However, the Bureau retains jurisdiction to review all mergers, including those that do not exceed the notification thresholds, and is increasingly monitoring and taking action with respect to non-notifiable mergers.

Waiting Periods

The Bureau must be notified of mergers that exceed these financial thresholds prior to closing. Closing is prohibited until 30 calendar days after the notification. In addition, the Bureau can extend this waiting period by issuing a supplementary information request (SIR), which is similar to a second request under the United States *Hart-Scott-Rodino Act*. The issuance of a SIR extends the waiting period until 30 calendar days after the merging parties have submitted information responsive to the requests in the SIR. Reviews of mergers where SIRs are issued often take between four to six months, or longer if remedies are required.

Substantive Review

Regardless of whether the transaction meets the notification thresholds, the Bureau will assess whether a merger is likely to prevent or lessen competition substantially. This occurs only where a merger is likely to create, maintain or enhance the ability of the merged entity, unilaterally or in coordination with other firms, to exercise market power. Among other things, the Bureau will consider the likely price effects of a merger, as well as impacts on product quality and the effects on innovation. Some key assessment factors the Bureau will consider include the parties' combined market shares, the degree of remaining competition, barriers to entry/expansion (including the dynamics of innovation and research and development in the particular industry), demand-side considerations (including buyer power) and regulatory oversight that might constrain the merging parties.

Efficiencies

The Act includes an express efficiencies defence that enables even mergers that are likely to prevent or lessen competition substantially to proceed so long as the efficiency gains from the mergers outweigh and offset the anticipated anti-competitive effects. This defence takes account of fixed-cost savings and dynamic efficiencies, not just variable cost savings. This defence may result in mergers being cleared in Canada with no remedies, or only limited remedies, as compared to other jurisdictions where no similar defence exists.

Resolution

Following its substantive review, the Bureau may issue a letter confirming it will take "no action" in respect of a merger (which gives the parties substantive comfort). Alternatively, if after its review the Bureau is concerned the merger is likely to prevent or lessen competition substantially, the Bureau may seek to negotiate changes to the merger (such as a divestiture or behavioural commitment) to address those concerns or apply to the Competition Tribunal for an order prohibiting all or part of the merger, among other things. There are also numerous interim steps available to the Bureau, such as permitting merging parties to close transactions but mandating that the businesses the Bureau has concerns about be placed into a "hold separate" arrangement.

Recent Trends in Merger Review

Mergers in the pharmaceutical industry have been an area of active enforcement for the Bureau, and the Bureau is expected to continue to closely scrutinize them.

Recent trends in pharmaceutical industry merger review in Canada include the following:

Market Definition

The Bureau's general approach is to define the markets in which the parties compete for the purpose of assessing a merger's competitive effect. The Bureau has no preferred methodology for defining markets in the pharmaceutical industry. In some cases, the Bureau has defined product markets by reference to a pharmaceutical product's molecule or active ingredient, the format in which a pharmaceutical product is supplied (e.g., injectable or table), dosage or some combination of these criteria. In every instance, the Bureau is focused on identifying the set of products that are substitutes from a demand perspective and applying the "hypothetical monopolist" test. From a geographic perspective, theBureau often accepts that in pharmaceutical industry mergers, the relevant markets are Canada-wide.

Coordinating Processes

The pharmaceutical industry mergers reviewed under the Act often involve global companies with significant assets or sales in Canada. These mergers are typically also subject to review in other jurisdictions, including the United States and the European Union. This requires coordination by competition lawyers to ensure that submissions made in one jurisdiction are consistent with the submissions made in other jurisdictions. In such cases, the Bureau will coordinate with agencies in these other jurisdictions and may request that waivers be provided to those agencies to permit the exchange of the merging parties' confidential information (the Bureau takes the position that it does not require a waiver under Canadian law). In addition, the Bureau has issued guidance outlining best practices on cooperation in cross-border merger investigations that call for, among other things, coordination on timing and outcome of cross-border mergers reviewed by these agencies.

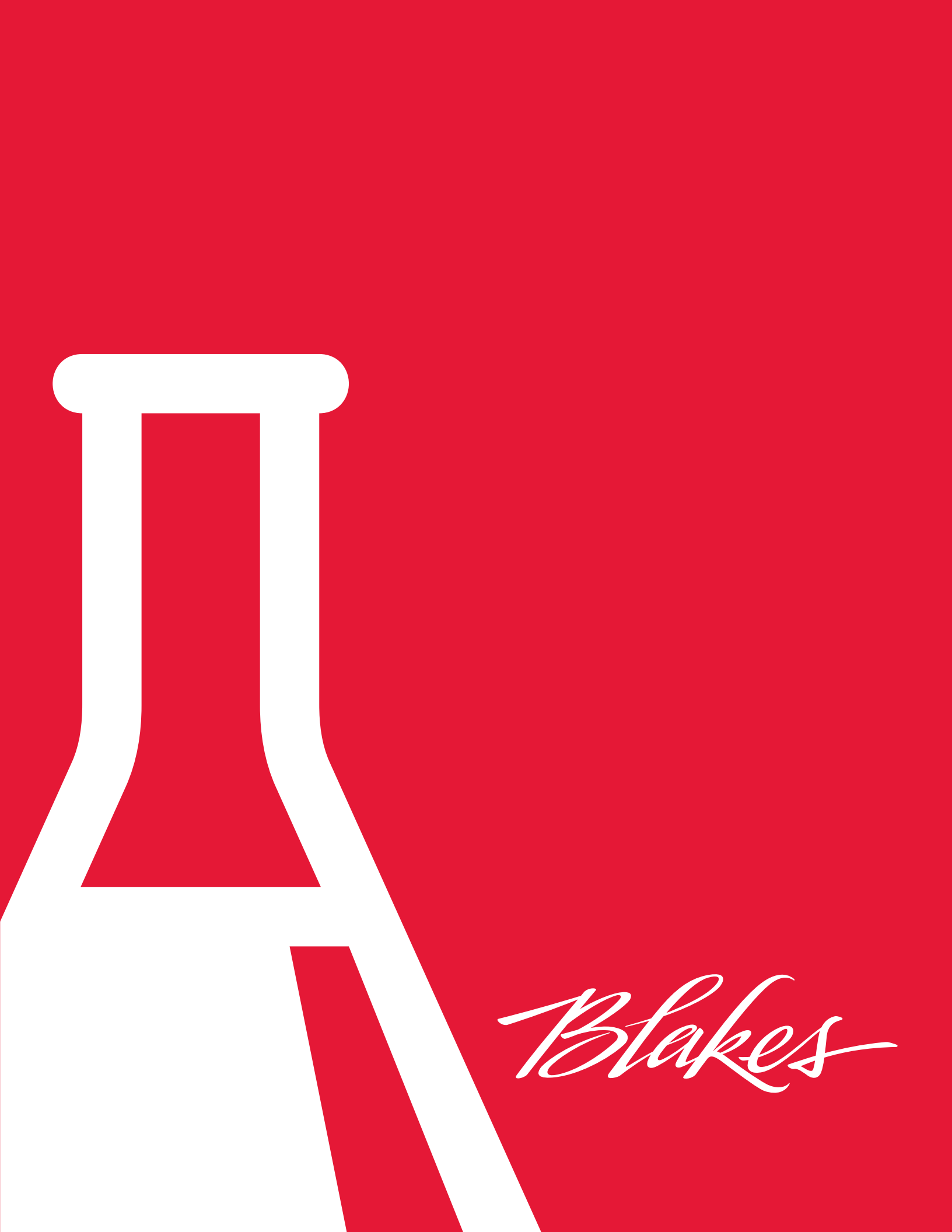
Coordinating Remedies

When the Bureau identifies concerns about a merger in the pharmaceutical industry, the same concern is sometimes shared by reviewing agencies in other jurisdictions. This often results in parties proposing the same remedies in Canada that they propose to other agencies. Where these remedies satisfy the agencies, the Bureau has taken different approaches. In some cases, the Bureau has required a consent agreement that is substantively identical to remedies imposed upon the merging parties in other jurisdictions. In other cases, it has simply concluded its review, noting that remedies imposed upon the parties in other jurisdictions are sufficient to address its concerns. The approach when remedies are coordinated across jurisdictions depends on the facts of the case, such as whether assets to be divested are located in Canada or when enforcement of the remedy necessitates the formalities of a consent agreement.

Conclusion

Participants in the pharmaceutical industry in Canada face myriad commercial, legal and regulatory challenges daily.

Careful planning and management can help minimize the burden associated with compliance with Canada's *Competition Act* and help participants in the pharmaceutical industry in Canada succeed.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