COMPETITION TRIBUNAL
TRIBUNAL DE LA CONCURRENCE

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OTTAWA, ONT. | # 10

File No. CT-2024-006

COMPETITION TRIBUNAL

IN THE MATTER OF the Competition Act, R.S.C. 1985, c. C-34 (the "**Act**");

AND IN THE MATTER OF an application by JAMP Pharma Corporation for an order pursuant to section 103.1 of the Act granting leave to bring an application under section 79 of the Act;

AND IN THE MATTER OF an application by JAMP Pharma Corporation for an order pursuant to section 79 of the Act;

BETWEEN:

JAMP PHARMA CORPORATION

Applicant

– and –

JANSSEN INC.

Respondent

AFFIDAVIT OF EMILY SEABY

(Pursuant to section 103.1 of the *Competition Act*)

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INDEX

I N D E X

1

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AFFIDAVIT OF EMILY SEABY

(Pursuant to section 103.1 of the *Competition Act*)

I, Emily Seaby, of the City of Toronto, in the Province of Ontario, **MAKE OATH AND SAY**:

1. I am a legal assistant employed by the firm Goodmans LLP ("Goodmans"), solicitors for JAMP Pharma Corporation Inc. ("JAMP"), and as such have knowledge of the matters to which I hereinafter depose, unless otherwise indicated.

2. Attached as **Exhibit "S1"** to my affidavit is a copy of a joint statement of the Food & Drug Administration and the Federal Trade Commission regarding a collaboration to advance competition in the biologic marketplace, dated February 3, 2020.

3. Attached as **Exhibit "S2"** to my affidavit is a copy of the Federal Trade Commission's brief as *Amicus Curiae* in *Teva v. Amneal*, Civil Action No. 2:23-cv-20964-JXN-MAH.

4. Attached as **Exhibit "S3"** to my affidavit is a copy of the Competition Bureau's Position Statement regarding Teva's acquisition of Allergan's generic pharmaceuticals business, dated April 18, 2016.

5. Attached as **Exhibit "S4"** to my affidavit is a copy of the Competition Bureau's report regarding the Generic Drug Sector Study, dated October 29, 2007.

6. Attached as **Exhibit "S5"** to my affidavit is a copy of the Competition Bureau's Abuse of Dominance Enforcement Guidelines, dated March 7, 2019.

7. Attached as **Exhibit "S6"** to my affidavit is a copy of the European Commission's press release titled: "Commission sends Statement of Objections to Teva over misuse of the patent system and disparagement of rival multiple sclerosis medicine", dated October 10, 2022.

8. Attached as **Exhibit "S7"** to my affidavit is a copy of the House of Commons' Standing Committee On Industry, Science And Technology report, titled "A Plan to Modernize Canada's Competition Regime", dated April 2002.

9. Attached as **Exhibit "S8"** to my affidavit is a copy of the 2022 Annual Report of the Patented Medicines Prices Review Board.

SWORN remotely by Emily Seaby, stated as being in the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on July 26, 2024, in accordance with O. Reg. 431/20, *Administering Oath or Declaration Remotely*

A Commissioner, etc.
Name: **Jonathan Wall**

Name: Emily Seaby

Exhibit “S1”

This is Exhibit “S1” referred to in the Affidavit of Emily Seaby, sworn before me this 26th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Jon Wall

Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace

February 3, 2020

The Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) have a long history of working collaboratively to protect American consumers. We have formally collaborated since 1954 to support the important missions of both FDA and FTC.[1]

Much of our collaborative work focuses on ensuring that advertising and other promotional communications for products subject both to FDA oversight and to FTC enforcement are truthful and non-misleading. Truthful and non-misleading advertising and promotional communications help foster competitive markets by allowing purchasers to compare products, prices, and benefits. In addition, ensuring that advertising and promotional communications about products subject to FDA regulation are truthful and non-misleading helps to protect and promote public health by enabling patients and health care providers to make decisions based on accurate information. This Statement details how FDA and FTC will work together to promote competitive markets for biological products and to take appropriate steps to address false or misleading statements and promotional communications by biological product (biologic) manufacturers.

Biologics have become a mainstay of modern medicine. These products are often more expensive than small molecule drugs, accounting for two percent of total prescription volume but 37 percent of total prescription drug spend in the United States.[2] Biologics comprise the fastest growing, and one of the most expensive, segments of prescription medicine spending.[3] Public and private insurers in the U.S. spent $125.5 billion on biologics in 2018 alone.[4]

Competition brings substantial benefits to consumers through lower prices, greater access to higher quality goods and services, and increased innovation. The 1984 Hatch Waxman

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[1] The agencies updated and replaced the original 1954 Working Agreement between the FTC and the FDA in 1971 with a memorandum of understanding. *See* Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18, 539 (Sept. 16, 1971).

[2] *See* IQVIA Inst. for Human Data Sci., Medicine Use and Spending in the U.S. 6 (April 2018), https://www.iqvia.com/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf (discussing specialty drug prevalence and spending); *accord* Medicare Payment Advisory Commission, A Data Book: Health Care Spending and the Medicare Program, 150 (June 2018), http://medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf?sfvrsn=0; Congressional Budget Office, Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid (Mar. 2019), https://www.cbo.gov/system/files/2019-03/55011-Specialty_Drugs_WP.pdf.

[3] Scott Gottlieb, Comm'r, FDA, Speech at America's Health Insurance Plans' (AHIP) National Health Policy Conference: Capturing the Benefits of Competition for Patients (Mar. 7, 2018), https://www.fda.gov/news-events/speeches-fda-officials/capturing-benefits-competition-patients-03072018 ("Taken together, biologics now account for about 40% of all U.S. drug spending -- and 70% of spending growth. . . ."); *see also* IQVIA, *supra* note 2.

[4] *See* IQVIA Inst. for Human Data Sci., Medicine Use and Spending in the U.S. 26 (May 2019), https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.

Amendments created an abbreviated approval process for generic versions of small molecule drugs. Competition from generic drugs has saved Americans hundreds of billions of dollars in drug costs.[5] Similarly, with these benefits of competition in mind, in 2010 Congress enacted the Biologics Price Competition and Innovation Act (BPCI Act) to foster competition for biologics.[6] The BPCI Act created an abbreviated pathway for biological products demonstrated to be biosimilar to or interchangeable with an FDA-licensed reference product. A biosimilar is a biological product that is highly similar to its reference product, a biological medication already approved by FDA. Biosimilars have no clinically meaningful differences from the reference product in terms of safety or effectiveness. Generally described, an interchangeable is a biosimilar to the reference product that meets additional requirements outlined in the BPCI Act. Additional information is needed to show that an interchangeable is expected to produce the same clinical result as the reference product in any given patient. Also, for a biological product administered more than once to patients, FDA will have evaluated the risk in terms of safety and reduced efficacy of switching back and forth between an interchangeable product and a reference product. An interchangeable product may be substituted for the reference product without the involvement of the prescriber.[7] The abbreviated pathway enables potentially shorter and less costly drug development programs for biosimilar and interchangeable products while maintaining FDA's high approval standards.

Biologics play a critical role in the treatment of many serious illnesses, including rare genetic disorders, autoimmune diseases, and cancer. For many of these conditions, there are no treatment alternatives. Supporting a competitive marketplace for biologics, including biosimilar and interchangeable products, is essential for improving patient access to medicines and potentially reducing health care costs. To date, FDA has approved twenty-six biosimilars, although business and intellectual property concerns have contributed to the delayed launch of some approved products.[8] Biosimilars marketed in the United States typically launched with initial list prices 15 to 35 percent lower than the list prices of the reference products.[9]

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[5] *See Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regulatory Reform, Commercial, and Antitrust Law of the H. Comm. on the Judiciary*, 115th Cong. (2017) (Prepared Statement of Markus H. Meier, Acting Director, Bureau of Competition, FTC at 5), https://www.ftc.gov/system/files/documents/public_statements/1234663/p859900_commission_testimony_re_at_concerns_and_the_fda_approval_process_house_7-27-17.pdf; Scott Gottlieb, *FDA Working to Lift Barriers to Generic Drug Competition*, FDA (June 21, 2017), https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-working-lift-barriers-generic-drug-competition.

[6] Biologics Price Competition and Innovation Act of 2009 ("BPCI Act"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (BPCI Act was enacted under Title VII of PPACA).

[7] More information about biosimilar and interchangeable products can be found at www.fda.hhs.gov/biosimilars.

[8] *See Biosimilar Product Information, FDA-Approved Biosimilar Products*, FDA (July 20, 2018), https://www.fda.gov/drugs/biosimilars/biosimilar-product-information (last visited Aug. 28, 2019); FTC, Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs 11 (July 16, 2018), https://www.ftc.gov/policy/advocacy/advocacy-filings/2018/07/statement-federal-trade-commission-department-health-human.

[9] *See* Mulcahy, *supra*, note 4; Gottlieb, *supra*, note 3; *see, e.g., Merck's Biosimilar Debuts at a 35% List Price Discount to Remicade*, P&T Community (July 24, 2017), https://www.ptcommunity.com/news/20170724/merck-s-biosimilar-debuts-35-list-price-discount-remicade; *accord* Ameet Sarpatwari, et. al., *The US Biosimilar Market:*

While the U.S. market for biosimilars is still maturing, research suggests that after market entry, biosimilars can generate significant price competition and consumer savings.[10] FTC's analysis similarly concludes that competition generated by biosimilars could generate significant consumer benefit.[11] Basic economic principles support the analyses: more competition leads to price reductions, increased consumer access and choice, and innovation.

FDA issued a Biosimilars Action Plan (BAP) in July 2018 that outlines four key strategies to accelerate biosimilar competition.[12] One key goal in the BAP is to support market competition by reducing "gaming" and other attempts to unfairly delay competition. Strengthening the partnership and interagency coordination between FDA and FTC will help each agency address and deter anticompetitive behavior in the U.S. market for biological products. Such behavior might include anticompetitive reverse payment agreements, abusive repetitive regulatory filings, or misuse of restricted drug distribution programs.

To deter anticompetitive practices, FDA recently issued final guidance for industry related to certain types of citizen petitions intended to delay FDA action on a generic or other abbreviated application.[13] This guidance will help FDA allocate resources efficiently when addressing petitions likely to obstruct entry of generic and biosimilar medications. FDA will also refer to FTC and highlight in FDA's annual report to Congress its determinations of petitions submitted with the primary purpose of delaying an approval.

Both FDA and FTC support competitive markets for biologics and have serious concerns about false or misleading statements and their negative impacts on public health and competition. False or misleading comparisons of reference products and biosimilars may constitute unfair or deceptive practices that undermine confidence in biosimilars. Both agencies want to ensure that health care professionals and patients receive truthful and non-misleading information about biological products. One focus of the agencies is false or misleading communications about biosimilars within their authorities. FDA will undertake efforts to educate health care professionals and patients about biosimilars and explain why people should have confidence in the safety and effectiveness of these FDA-approved products just as they would the reference products. The agencies believe these actions will facilitate a more competitive marketplace.

Stunted Growth and Possible Reforms, 105 Clinical Pharmacology & Therapeutics 92, 94 (2019) (as of Aug. 2018, biosimilar competition had resulted in discounts up to 57% off the reference biologic's list price).

[10] S*ee also* QuintilesIMS, The Impact of Biosimilar Competition in Europe (May 2017), https://www.medicinesforeurope.com/wp-content/uploads/2017/05/IMS-Biosimilar-2017_V9.pdf.

[11] *See* FTC, *supra* note 8, at 9.

[12] FDA, Biosimilars Action Plan: Balancing Innovation and Competition 5-9 (July 2018), https://www.fda.gov/media/114574/download.

[13] FDA, Docket No. FDA-2009-D-008, Final Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (Sept. 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/citizen-petitions-and-petitions-stay-action-subject-section-505q-federal-food-drug-and-cosmetic-act-0.

Joint Goals

FDA and FTC are collaborating to support appropriate adoption of biosimilars, deter false or misleading statements about biosimilars, and deter anticompetitive behaviors in this industry.

We jointly identified four goals to help in this effort:

1. **FDA and FTC will coordinate to promote greater competition in biologic markets.**

    - The agencies concur that more robust competition can help reduce the costs of biologics and facilitate increased patient access to important therapies.

    - FDA and FTC will cooperate in efforts to facilitate biologics competition to the extent possible.

    - FDA will develop materials to educate consumers and providers about biosimilars.

    - FDA and FTC will collaborate on future public outreach efforts, including sponsoring a public meeting to discuss competition for biologics.

2. **FDA and FTC will work together to deter behavior that impedes access to samples needed for the development of biologics, including biosimilars.**

    - FDA and FTC will collaborate to identify and deter tactics used to prevent or impede access to samples of the reference product that the prospective biosimilar applicant needs for testing to be licensed as a biosimilar or interchangeable biosimilar.

    - To facilitate such collaboration, FDA and FTC will evaluate whether additional information sharing arrangements are warranted.

3. **FDA and FTC intend to take appropriate action against false or misleading communications about biologics, including biosimilars, within their respective authorities.**

    - FDA and FTC, as authorized by their respective statutes, will work together to address false or misleading communications about biologics, including biosimilars. In particular, if a communication makes a false or misleading comparison between a reference product and a biosimilar in a manner that misrepresents the safety or efficacy of biosimilars, deceives consumers, or deters competition, FDA and FTC intend to take appropriate action within their respective authorities. FDA intends to take appropriate action to address such communications where those communications have the potential to impact public health.

    - FDA intends to use its authority under the Food, Drug, and Cosmetic Act to address false or misleading communications subject to FDA jurisdiction. FTC intends to use

its authority under the Federal Trade Commission Act to address unfair or deceptive acts or practices not subject to FDA jurisdiction.

- FDA is publishing a draft guidance outlining considerations for FDA-regulated advertisements and promotional labeling that contains information about biologic products.

4. FTC will review patent settlement agreements involving biologics, including biosimilars, for antitrust violations.

- Pursuant to the Patient Right to Know Drug Prices Act, Public Law No. 115-263 (Oct. 10, 2018), codified at 21 U.S.C.A. § 355, the FTC obtains and reviews patent settlement agreements between reference product and biosimilar manufacturers. This law extends a 2003 law requiring that drug manufacturers notify U.S. antitrust authorities of patent settlement agreements. This notification allows FTC to evaluate whether these agreements include, among other things, anticompetitive reverse payments that slow or defeat the introduction of lower-priced medicines, including biosimilars. Such review will occur in the same manner that FTC has been reviewing patent settlement agreements between brand and generic drug manufacturers.

- FDA and FTC will collaborate on efforts to ensure biosimilar development and uptake are not hindered by other anticompetitive practices.

We look forward to our continued work together to facilitate a more competitive biological product marketplace.

Signatures

Stephen M. Hahn, M.D.	**Joseph J. Simons,**
Commissioner of Food and Drugs,	**Chair,**
Food and Drug Administration	**Federal Trade Commission**

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

The FTC is an independent agency charged by Congress with protecting the interests of consumers by enforcing competition and consumer protection laws. It exercises primary responsibility for civil antitrust enforcement in the pharmaceutical industry. The FTC also seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices.

Exhibit “S2”

This is Exhibit “S2” referred to in the Affidavit of Emily Seaby, sworn before me this 26th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Jon Wall

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., AND TEVA PHARMACEUTICALS USA, INC. Plaintiffs, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, AND AMNEAL PHARMACEUTICALS INC. Defendants.	Civil Action No. 2:23-cv-20964-JXN-MAH

FEDERAL TRADE COMMISSION'S BRIEF AS AMICUS CURIAE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Regulations

INTRODUCTION

Listing a patent in the Orange Book gives a brand pharmaceutical company a powerful tool—the ability to trigger a 30-month stay of approval of a generic competitor product. The Federal Trade Commission (FTC or Commission) has a long history of working to address improper Orange Book patent listings because of how those listings thwart competition from lower-cost generic drugs.

Amneal alleges that Teva's improper listing of patents for dose counters and inhaler devices in the Orange Book is delaying entry of its less expensive generic asthma inhalers from summer 2024 to early 2026.[1] Millions of Americans rely on asthma inhalers for life-saving treatment, and the patent on the active ingredient in many asthma inhalers—albuterol—expired in 1989. Although albuterol has long been off-patent, there remains little generic competition in the market for asthma inhalers, in part because brand manufacturers improperly list patents that claim device-related aspects of asthma inhalers, like dose counters, to block competition. As a result, asthma inhalers often cost hundreds of dollars, although they would likely cost significantly less in a more competitive market.

Because improper Orange Book listings can effectively block competition, Congress carefully prescribed what types of patents must be listed in the Orange

[1] *See* Def.'s Answer, Affirmative Defenses, and Countercl. to Pl.s' First Am. Compl., ECF No. 12 ¶¶ 121-22, 130 ("Amneal Countercl."). At this stage in the proceedings, these allegations are accepted as true.

Book, permitting only drug substance, drug product, and method of use patents on Food and Drug Administration (FDA) approved drugs to be listed. Here, however, Teva has triggered a 30-month stay based on inhaler and dose counter device patents that, on their face, are not specific to any FDA-approved drug. Indeed, one of the asserted patents (U.S. Patent No. 10,561,808) has been listed in the Orange Book for 21 different products spanning six separate new drug applications (NDA) and four active ingredients.[2]

In the FTC's view, device patents that do not mention any drug in their claims do not meet the statutory criteria for Orange Book listing, and a device patent that is improperly listed in the Orange Book must be delisted. Should a brand manufacturer not voluntarily delist an improperly listed device patent, it is well within the powers of a district court to compel delisting. Here, Teva has listed device patents in the Orange Book that do not mention any drug in their claims. If the Court agrees that such patents do not meet the listing requirements, it should grant Amneal's motion for judgment on the pleadings and order Teva to delist the patents at issue—clearing the way for Americans to access less expensive asthma inhalers.

[2] *See* U.S. Dep't Health & Hum. Servs., Food & Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations* ADA 7, 39-40, 178-188 (44th ed. 2024) ("Orange Book").

Teva's arguments opposing delisting are unavailing and inconsistent with the statute. Indeed, in a strikingly similar case, the First Circuit rightly held it improper to list a device patent that did not mention the active ingredient or the drug product in the claims. Moreover, Teva's novel argument that the delisting provision immunizes its conduct from the antitrust laws is wrong. Courts and the FTC, the expert body charged with protecting fair competition in pharmaceutical markets, have long recognized that improper Orange Book listings can be actionable under the antitrust laws.

INTEREST OF THE FEDERAL TRADE COMMISSION

The FTC is an independent agency charged by Congress with enforcing competition and consumer protection laws.[3] It exercises primary responsibility for federal antitrust enforcement in the pharmaceutical industry.[4] The Commission has substantial experience evaluating pharmaceutical competition under the Hatch-Waxman Act and has brought numerous enforcement actions challenging anticompetitive abuses of the Hatch-Waxman framework.[5]

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[3] 15 U.S.C. §§ 41-58.

[4] For a recent summary of the FTC's actions in the pharmaceutical industry, *see* Bradley S. Albert et al., Overview of FTC Actions in Pharm. Products and Distrib., Fed Trade Comm'n (Jan. 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/Overview-Pharma.pdf.

[5] *See, e.g.*, *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015); *Impax Labs, Inc. v. FTC*, 994 F.3d 484 (5th Cir. 2021); *FTC v. AbbVie Inc.*, 976 F.3d 327 (3d Cir. 2020); *FTC v. Shkreli*, 581 F. Supp. 3d 579 (S.D.N.Y. 2022).

The FTC has long been concerned about abusive Orange Book listings because of how improper listings may delay and deter competition from less expensive generic drugs. The Commission first examined the effect of Orange Book listings on competition as part of a 2002 study, identifying numerous instances in which companies used the 30-month stay to block competition.[6] Around the same time, the FTC successfully settled an action under the antitrust laws against Biovail Corporation for, among other things, wrongfully listing a patent in the Orange Book to block generic competition.[7]

The FTC has also regularly filed amicus briefs in private litigation, explaining how improper Orange Book listings can violate the antitrust laws.[8] In September 2023, the FTC issued a policy statement, supported by the FDA, warning that improperly listing patents in the Orange Book may constitute illegal

[6] *See* Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study, 39-52 (2002) ("FTC Study on Generic Drug Entry Before Patent Expiration"), https://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study.

[7] Decision & Order, *In re Biovail Corp.*, FTC Dkt. No. C-4060 8 (Oct. 2, 2002).

[8] *See* Mem. of Law for Fed. Trade Comm'n as Amicus Curiae, *In re: Buspirone Patent Litig.*, No. 1:01-md-1410, ECF No. 31 (S.D.N.Y. Jan. 8, 2002); Mem. of Law for Fed. Trade Comm'n as Amicus Curiae, *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 1:21-cv-691, ECF No. 227 (D. Del. Nov. 15, 2022); Mem. of Law for Fed. Trade Comm'n as Amici Curiae, *Mylan Pharms. Inc. v. Sanofi-Aventis U.S. LLC*, No. 2:23-cv-00836, ECF No. 64 (W.D. Pa. Nov. 21, 2023).

monopolization under section 2 of the Sherman Act as well as an unfair method of competition under section 5 of the FTC Act.[9]

Last November, the FTC's Bureau of Competition sent warning letters to ten drug manufacturers notifying them of more than 100 Orange Book patent listings that FTC staff believes to be improper ("warning letters").[10] The warning letters identified patents listed on 13 inhaler products and four epinephrine injector pens, among other FDA-approved products. Two of the warning letters were sent to Teva and identified the five patents at issue in this case (the "asserted patents") as

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[9] *See* Fed. Trade Comm'n, Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book, at 5-6 (Sept. 14, 2023) ("FTC Orange Book Policy Statement"), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; *see also* Fed. Trade Comm'n, Press Release, FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book' (Sep. 14, 2023) ("FTC Press Release re: Orange Book Policy Statement"), https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug ("The FDA appreciates and supports the FTC's efforts to examine whether brand drug companies are impeding generic drug competition by improperly listing patents in the Orange Book,' said FDA Commissioner Robert M. Califf, M.D.").

[10] *See* Fed. Trade Comm'n, Press Release, FTC Challenges More Than 100 Patents As Improperly Listed in the FDA's Orange Book (Nov. 7, 2023) (FTC Press Release re: Improper Orange Book Listings"), https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book.The patents identified in the warning letters should not be interpreted as an exclusive or exhaustive list of patents that the FTC believes are wrongfully listed, and companies that did not receive a letter in November 2023 should not assume the FTC views their listings as proper. The FTC continues to scrutinize whether additional patents are improperly listed, and all companies have an ongoing responsibility to ensure their listings are lawful.

well as 37 additional Teva patent listings on inhalers.[11] The letters notified Teva and other drug companies that the FTC was utilizing FDA's regulatory patent listing dispute process to challenge the improper listings, while retaining the right to take further action against the companies that the public interest may require, including investigating the conduct as an unfair method of competition under section 5 of the FTC Act.

In response to the warning letters, several companies, including GlaxoSmithKline, Kaleo, Inc., and Impax Laboratories LLC, delisted 14 patents across six NDAs. Meanwhile, AstraZeneca, Boehringer Ingelheim, and GlaxoSmithKline announced that they would reduce patient out-of-pocket costs for all of their asthma inhalers to $35 a month.[12] Following the warning letters,

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[11] *See* Letter from Rahul Rao, Dep. Dir., Bur. Competition, Fed. Trade Comm'n to Teva Branded Pharm. Prods. R&D, Inc. Regarding Improper Orange Book-Listed Patents for QVAR 40, ProAir HFA, ProAir DigiHaler (Nov. 7, 2023) ("Teva Warning Letter"), https://www.ftc.gov/system/files/ftc_gov/pdf/teva-branded-pharma-orange-book.pdf (disputing propriety of 35 patent listings, comprised of 18 patents across 3 inhaler products); Letter from Rahul Rao, Dep. Dir., Bur. Competition, Fed. Trade Comm'n to Norton (Waterford) Ltd. Regarding Improper Orange Book-Listed Patents for QVAR RediHaler (Nov. 7, 2023) ("Norton Warning Letter"), https://www.ftc.gov/system/files/ftc_gov/pdf/norton-orange-book.pdf (disputing propriety of 7 patent listings on 1 inhaler product).

[12] *See* Press Release, AstraZeneca, AstraZeneca caps patient out-of-pocket costs at $35 per month for its US inhaled respiratory portfolio (Mar. 18, 2024), https://www.astrazeneca-us.com/media/press-releases/2024/astrazeneca-caps-patient-out-of-pocket-costs-at-35-per-month-for-its-us-inhaled-respiratory-portfolio.html; Press Release, Boehringer Ingelheim, Boehringer Ingelheim caps patient out-of-pocket costs for its inhaler portfolio at $35 per month (Mar. 7,

numerous members of Congress also launched inquiries into the drug companies' Orange Book listings and other potentially anticompetitive practices.[13]

The warning letters to Teva explained FTC staff's belief that the patents at issue in this case—plus many others—are improperly listed in the Orange Book.

2024), https://www.boehringer-ingelheim.com/us/press-releases/boehringer-ingelheim-caps-patient-out-of-pocket-costs-inhaler-portfolio; Press Release, GlaxoSmithKline, GSK announces cap of $35 per month on U.S. patient out-of-pocket costs for its entire portfolio of asthma and COPD inhalers (Mar. 20, 2024), https://us.gsk.com/en-us/media/press-releases/gsk-announces-cap-of-35-per-month-on-us-patient-out-of-pocket-costs-for-its-entire-portfolio-of-asthma-and-copd-inhalers. While the Commission welcomes voluntarily reductions in patients' out-of-pocket costs, doing so is not a substitute for removing improper patent listings, as such listings may delay competition from generics with lower list prices.

[13] *See* Press Release, U.S. Sen. Comm. On Health, Educ. Labor and Pensions, Chairman Sanders, Baldwin, Luján, Markey Launch HELP Committee Investigation into Efforts by Pharmaceutical Companies to Manipulate the Price of Asthma Inhalers (Jan. 8, 2024), https://www.help.senate.gov/chair/newsroom/press/news-chairman-sanders-baldwin-lujan-markey-launch-help-committee-investigation-into-efforts-by-pharmaceutical-companies-to-manipulate-the-price-of-asthma-inhalers; Letter from Sen. Bernie Sanders et al. to Pascal Soriot, Exec. Dir. & Chief Exec. Off., AstraZeneca PLC (Jan. 8, 2024), https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-AstraZeneca.pdf; Letter from Sen. Bernie Sanders et al. to Hubertus von Baumbach, Chairman of the Bd. Of Managing Dirs., Boehringer Ingelheim Int'l GmbH (Jan. 8, 2024), https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-Boehringer-Ingelheim.pdf; Letter from Sen. Bernie Sanders et al. to Emma Walmsley, Chief Exec. Off., GSK (Jan. 8, 2024), https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-Boehringer-Ingelheim.pdf; Letter from Sen. Bernie Sanders et al. to Richard Francis, Pres. & Chief Exec. Off., Teva Pharm. Indus. Ltd. (Jan. 8, 2024), https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-Teva.pdf.

Rather than heed this warning, Teva re-certified the propriety of the 42 patent-listings identified in the warning letter, including each of the five patents listed for ProAir HFA that Teva asserts in this case.[14] Moreover, Teva re-certified those Orange Book listings despite the underlying device patents' failure to mention any drug at all in their claims. According to Amneal's counterclaims, Teva is using these improper Orange Book listings to restrict competition and delay Amneal from making less expensive generic inhalers available to the American public.[15]

The FTC submits this amicus brief because device patents improperly listed in the Orange Book can undermine fair competition, shutting out generics from the market and depriving Americans of access to lower-cost drugs.[16]

BACKGROUND

I. The Statutory and Regulatory Framework

Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act,[17] with the aim of "balanc[ing] two

[14] *See* Teva Warning Letter, *supra* note 11; Norton Warning Letter, *supra* note 11.
[15] Amneal Countercl., ECF No. 12 ¶¶ 101-05; 120-25.
[16] As the FTC stated in its policy statement, the Commission will "use all its tools to halt unlawful business practices that contribute to high drug prices." FTC Orange Book Policy Statement, *supra* note 9. In filing this amicus brief, the FTC does not disclaim or waive its right to bring an enforcement action against Teva or any other company that the FTC believes may continue to improperly list patents in the Orange Book.
[17] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

competing interests."[18] On the one hand, the Hatch Waxman Act "encourag[es] research and innovation" by protecting brand drug companies' patent interests associated with drugs approved through the NDA.[19] On the other, the Act seeks to facilitate getting lower-cost "generic drugs on the market in a timely fashion"[20] through mechanisms like the abbreviated new drug application (ANDA), which provides an expedited pathway for approval of generic drugs.[21]

The Hatch-Waxman framework includes provisions "that encourage the quick resolution of patent disputes" for certain types of patents.[22] The Hatch-Waxman amendments and FDA regulations instruct brand manufacturers to submit information about certain patents for their NDA products to the FDA for publication in a compendium entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book."[23] Listing a patent in the Orange Book can be extremely valuable because it gives brand

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[18] *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 5 (1st Cir. 2020) (citing Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36676 (June 18, 2003)

[19] *Id*.

[20] *Id.* at 11 (citing 68 Fed. Reg. at 36676).

[21] *See* 21 U.S.C. § 355(j).

[22] *AbbVie*, 976 F.3d at 339.

[23] *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405-6 (2012).

manufacturers the power to trigger an automatic delay of FDA approval of competing generic products, generally for 30 months.

When a drug company seeks to market a generic version of a brand drug for which there are patents listed in the Orange Book, the company must provide a "certification" for each listed patent "which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval."[24] For non-expired patents, the generic company can file a "paragraph IV" certification asserting that the brand company's patent is invalid or will not be infringed by the generic drug.[25] Notice of the certification triggers an immediate right for the brand manufacturer to sue for infringement.[26] When a brand manufacturer brings such an infringement suit within 45 days after receiving notice for a patent that was submitted to FDA prior to the submission of the ANDA, as Teva did here, the FDA's approval of the generic manufacturer's ANDA is automatically stayed for

[24] 21 U.S.C. 355(j)(2)(A)(vii); *see also* 21 C.F.R. § 314.95(a).

[25] *See* 21 U.S.C. § 355(j)(2)(A)(vii). If the generic is not contending the patents are invalid or not infringed, it would simply file a "paragraph III" certification signifying it will wait to come to market until patent expiry. *See id*.

[26] There is no right to file an infringement suit in response to a paragraph IV certification if the patent was obtained by fraud on the U.S. Patent and Trademark Office or if the infringement suit would be objectively baseless. *See*, *e.g.*, *AbbVie Inc.*, 976 F.3d at 361 ("[W]e must not immunize a brand-name manufacturer who uses the Hatch-Waxman Act's automatic, 30-month stay to thwart competition. Doing so would excuse behavior that Congress proscribed in the antitrust laws.").

30 months.[27] Unlisted patents can still be enforced after the generic product launches.[28]

Given the significant consequences of listing a patent in the Orange Book, Congress put strict limits on the types of patents that may be listed. The Hatch-Waxman Act included Orange Book listing provisions that require brand manufacturers to submit listing information for specific types of patents.[29] For over two decades, FDA regulations have further specified that patents eligible for listing "consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents."[30] More recently, Congress enacted the Orange Book Transparency Act of 2020 (OBTA), which amended the listing provisions to state that a patent should be listed only if a "claim of patent infringement could reasonably be asserted" and the patent:

> (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or

[27] 21 U.S.C. § 355(j)(5)(B)(iii). If the patent is held infringed, that stay of approval is automatically extended until the patent's expiration date; *compare eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 390-1 (2006) (holding prevailing patent plaintiff must normally meet traditional four-factor test to obtain permanent injunction).

[28] *See Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1350 (Fed. Cir. 2002) (denying collateral estoppel because "infringement under [35 U.S.C] § 271I(2)(A) by submission of an ANDA is not synonymous with infringement under § 271(a) by a commercial product").

[29] Pub. L. No. 98-417, Stat. 1585.

[30] 21 C.F.R. § 314.53(b)(1) (2003).

> (II) claims a method of using such drug for which approval is sought or has been granted in the application.[31]

Further, the listing provisions provide that information on patents that do not meet these requirements "shall not be submitted."[32]

NDA holders have a responsibility to ensure that Orange Book patent listings meet the statutory requirements. The FDA considers its role in this listing process to be "purely ministerial."[33] It does not "police the listing process by analyzing whether the patents listed by NDA applicants actually claim the subject drugs or applicable methods of using those drugs."[34]

Although the FDA does not independently evaluate the patents submitted for listing in the Orange Book, it provides a process under which any person may "dispute[] the accuracy or relevance of patent information submitted."[35] Under that process, the FDA relays the dispute statement to the brand manufacturer. The brand manufacturer must respond within 30 days by instructing the FDA to delist the patent or amend the patent information, or by re-certifying under penalty of

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[31] 21 U.S.C. § 355(b)(1)(A)(viii).
[32] *Id*. § 355(c)(2).
[33] *Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 458-59 (D.N.J. 2003); *see also* U.S. Food & Drug Admin., Report to Congress: The Listing of Patent Information in the Orange Book, at 5 (Jan. 2022). https://www.fda.gov/media/155200/download ("FDA serves a ministerial role with regard to the listing of patent information").
[34] *Apotex v. Thompson*, 347 F.3d 1335, 1349 (Fed. Cir. 2003).
[35] 21 C.F.R. § 314.53(f).

perjury the propriety of the listings.[36] The FDA does not assess or take any other action on the dispute and will not change or remove the Orange Book listing unless the brand manufacturer instructs the FDA to do so in its response.[37]

In 2003, Congress authorized generic manufacturers that are sued for infringement of Orange Book-listed patents to bring a counterclaim seeking to remove the listing.[38] In addition to this delisting counterclaim, courts and the FTC have long recognized (both before and after the adoption of the delisting counterclaim provision) that improper Orange Book listings can also be actionable under the antitrust laws.[39] The FDA supports the FTC's efforts to examine whether brand drug companies are impeding generic drug competition by improperly listing patents in the Orange Book.[40]

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[36] *See id.*

[37] *See id.*

[38] *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I).

[39] *See, e.g.*, *Lantus*, 950 F.3d at 6-7, 15 (finding improper listing of component device patent may support Section 2 Sherman Act claim); *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 315 (D.R.I. 2019) (ruling "sham Orange Book listing claim" under Section 2 of the Sherman Act may proceed to trial); *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 531 (D.N.J. 2004) ("there exists no regulatory scheme [for Orange Book listings] so extensive as to supplant antitrust laws"); *see also* FTC Study on Generic Drug Entry Before Patent Expiration, *supra* note 6, at 1; FTC Orange Book Policy Statement, *supra* note 9, at 1.

[40] *See* FTC Press Release re: Orange Book Policy Statement, *supra* note 9.

II. Teva Continues to Improperly List Patents in the Orange Book—Including the Asserted Patents—Despite FTC Staff Warnings

In November 2023, the FTC's Bureau of Competition sent letters to ten brand manufacturers informing them that FTC staff have opted to use the FDA's process to dispute over 100 Orange Book listings.[41]

In response, four brand drug manufacturers requested that the FDA remove from the Orange Book virtually all their patent listings identified by the FTC.[42] Several of those companies delisted asthma inhaler device patents and device component patents with claims that resemble the asserted patents in this case (i.e., device or device component patents that do not mention the active ingredient or the drug product that is the subject of the NDA in the patent claims).[43]

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[41] FTC Press Release re: Improper Orange Book Listings, *supra* note 10.

[42] *See* U.S. Food & Drug Admin., *Patent Listing Disputes* (current through Mar. 8, 2024), https://www.fda.gov/media/105080/download (noting changes in the patent listings for Kaleo Inc., Impax Laboratories LLC, GlaxoSmithKline Intellectual Property Development Limited, and Glaxo Group Limited). All told, these four manufacturers voluntarily delisted fourteen patents across six NDAs, with one patent being listed for three different applications.

[43] For example, GSK removed listings for patents on an "actuation indicator" (U.S. Patent No. 7,500,444), a "dose counter for use with a medicament dispenser" (U.S. Patent No. 8,113,199), a "medicament dispenser" (U.S. Patent No. 8,161,968), and a "manifold for use in a medicament dispenser" (U.S. Patent No. 8,534,281). *Compare* Letter from Rahul Rao, Dep. Dir., Bur. Competition, Fed. Trade Comm'n to GlaxoSmithKline Intell. Prop. Dev. Ltd (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/glaxosmithkline-orange-book.pdf, *and* Letter from Rahul Rao, Dep. Dir., Bur. Competition, Fed. Trade Comm'n to Glaxo Group Ltd (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/glaxo-group-orange-book.pdf, *with*

Teva, however, did not delist or amend any of the 42 patent-listings disputed by the FTC, including the asserted patents in this case.[44] Each of the asserted patents were listed in the Orange Book during the period from 2012 to 2022.[45] The patents are device or device component patents that claim a dose counter or an inhaler that includes a dose counter.[46] On their face, none of these patents mention any drug in their claims, much less the active ingredient in ProAir HFA, albuterol sulfate.[47] Notably, the patent covering albuterol sulfate expired in 1989.[48]

Patent No.	Patent Title	List Date
8,132,712	Metered-dose inhaler	Mar. 27, 2012
9,463,289	Dose counters for inhalers, inhalers and methods of assembly thereof	Nov. 8, 2016
9,808,587	Dose counter for inhaler having an anti-reverse rotation actuator	Nov. 16, 2017
10,561,808	Dose counter for inhaler having an anti-reverse rotation actuator	Mar. 19, 2020
11,395,889	Dose counter for inhaler having an anti-reverse rotation actuator	Aug. 19, 2022

U.S. Food & Drug Admin., *Patent Listing Disputes*, *supra* note 42, and *Delisted Patents*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/scripts/cder/ob/search_patent.cfm?listed=delisted (last updated Mar. 20, 2024).

[44] *Compare* Teva Warning Letter, *supra* note 11 and Norton Warning Letter, *supra* note 11 *with* U.S. Food & Drug Admin., *Patent Listing Disputes*, *supra* note 42.

[45] Pl.'s Am. Compl., ECF No. 7, Exs. A-E.

[46] *See id.*

[47] *See id.*; *see also* Orange Book (44th ed. 2024), *supra* note 2, at ADA 7(listing active ingredient of ProAir HFA as albuterol sulfate).

[48] Orange Book AD 6 (7th ed. 1987) (referencing U.S. Patent No. 3,644,353) (on file with Hyman, Phelps, & McNamara PC, *The Orange Book Archives, 1987, 7th Ed.*, https://thefdalawblog.com/wp-content/uploads/2020/06/OB-Annual-1987-7th-Ed.pdf).

Each of the asserted patents is also listed in the Orange Book for other Teva products.[49] For example, Teva has listed U.S. Patent No. 10,561,808 on a dose counter in the Orange Book for *21 different approved drugs*, many of which contain entirely different active ingredients from ProAir HFA.[50]

Despite receiving warning letters from the FTC's Bureau of Competition, Teva continues to list device and device component patents that, on their face, do not mention any drug in their claims. As a result, Teva can trigger—and here, has in fact triggered—a 30-month stay that blocks competition from less expensive generic inhalers solely based on these patents. In this case, Amneal submitted its ANDA seeking approval to market a generic version of ProAir HFA on August 24, 2023, and alleges that absent the 30-month stay, it could launch its less expensive competitor asthma inhaler as early as this summer.

ARGUMENT

The FTC believes this Court should grant Amneal's motion for a judgment on the pleadings as to counterclaim counts 1-5 regarding Teva's improper Orange Book listings. To aid the court in its analysis of the other federal law counterclaims, the FTC also explains how improper Orange Book listings harm

[49] Amneal Countercl., ECF No. 12 ¶ 86.
[50] *See* Orange Book (44th ed. 2024), *supra* note 2, at ADA 7, 39-40, 178-188.

fair competition and can trigger antitrust liability, and why *Trinko* does not apply to Amneal's counterclaims.

I. Drug Manufacturers Cannot Lawfully List Device Patents That Are Not Limited to Either the Active Ingredient or the Approved Product

The statutory listing provisions and related regulations require that, to be properly listed in the Orange Book, a patent must "claim[] the drug for which the applicant submitted the [NDA]" and also be either "a drug substance (active ingredient) patent or a drug product (formulation or composition) patent."[51] Alternatively, the patent may claim a "method of using such drug for which approval is sought or has been granted in the application."[52] Here, Teva listed the asserted patents in the Orange Book as "drug product" patents,[53] and it is undisputed that these patents are not "drug substance" or "method of use" patents.

Teva contends that the asserted patents qualify for the second category—drug product. However, a device or device component patent that does not mention any drug in its claims is not a "drug product (formulation or composition) patent." Rather, FDA regulations instruct manufacturers to "submit information only on those patents that claim the drug product, as is defined in [21 C.F.R.] § 314.3, that

[51] 21 U.S.C. § 355(b)(1)(A)(viii). *See also* 21 C.F.R. § 314.53(b)(1).
[52] *Id.*
[53] Pl.'s Br. In Supp. Mot., ECF No. 28, at 6 ("There are nine unexpired patents listed in the Orange Book for ProAir® HFA, each listed as a drug product patent.") ("Teva Br.").

is described in the pending or approved NDA."[54] In turn, § 314.3 defines "drug product" as "a finished dosage form, e.g., tablet, capsule, or solution, *that contains a drug substance*, generally, but not necessarily, in association with one or more other ingredients."[55] Together, these provisions mean that brand drug manufacturers may list as "drug product (formulation or composition) patents" only those that claim the finished dosage form containing the drug substance of the relevant NDA.[56] The asserted patents do not meet this criterion because they are device and device component patents untethered from any drug—much less the ProAir HFA albuterol sulfate formulation.[57]

As the FDA stated in its 2003 rulemaking on patent submissions and listing requirements, for drug product patent listings, "[t]he *key factor* is whether the patent being submitted claims the finished dosage form of the approved drug

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[54] 21 C.F.R. § 314.53(b)(1).

[55] 21 C.F.R. § 314.3(b) (emphasis added).

[56] 21 C.F.R. § 314.53(b)(1). The FDA's 2016 regulations made some "Technical Corrections to Regulatory Concepts" including modifying the text of § 314.53(b)(1) to reference "the drug product" instead of "a drug product." This was intended "to clarify that for patents that claim a drug product, the applicant must submit information only on those patents that claim the drug product, as is defined in § 314.3, that is described in the pending or approved NDA." *See* Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69580, 69631 (Oct. 6, 2016).

[57] Amneal argues device patents are not listable in the Orange Book. Def.'s Br. In Supp. Mot., ECF No. 48, at 14-21 ("Amneal Br."). Setting aside for present purposes whether device patents are *ever* listable, the FTC's view is that device and device component patents that do not claim the active ingredient or drug product that is the subject of the NDA are not listable.

product."[58] Here, the drug substance that was the subject of Teva's NDA for ProAir HFA is albuterol sulfate, and its finished dosage form is "metered aerosol."[59] The claims of the asserted patents mention neither albuterol sulfate nor the ProAir HFA albuterol sulfate metered aerosol. A comparison to one of Teva's actual formulation patents—which expired long ago—is illuminating. For example, claim 2 of U.S. Patent No. 5,695,743 claims "[a]n aerosol formulation comprising: (a) a therapeutically effective amount of [albuterol]; and (b) a propellant . . . comprising 1,1,1,2-tetrafluoroethane . . . ." This patent appears to have been properly listed, as this claim specifies the particular drug product—a metered aerosol formulation including the drug substance—for which Teva received approval. In contrast, the asserted patents do not even mention any elements of the formulation.

The First Circuit's decision in *In re Lantus Direct Purchaser Antitrust Litigation*, which similarly considered a device component patent and held its listing improper, is instructive.[60] In *Lantus*, the First Circuit considered an Orange Book listing for a combination drug/device product called Lantus SoloSTAR, a

[58] 68 Fed. Reg. at 36680 (emphasis added).
[59] *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Product Details for NDA 021457*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=021457#22991 (last visited Mar. 21, 2024).
[60] 950 F.3d at 1.

"pre-filled drug delivery system" that dispenses insulin glargine to the patient—i.e., an insulin injector pen.[61] That patent claimed "aspects of a 'drive mechanism' that serves as a part of the SoloSTAR drug injector pen."[62] The claims of the patent listed in the Orange Book for SoloSTAR did not mention the active ingredient insulin glargine or the drug product for which the NDA was submitted, Lantus SoloSTAR.[63] The First Circuit held that Sanofi's patent was improperly listed, reasoning that "[t]he statute and regulations clearly require that only patents that claim the drug for which the NDA is submitted should be listed in the Orange Book" and a patent that "neither claims nor even mentions the [active ingredient] or the [approved drug], does not fit the bill."[64] The Teva listings at issue here are strikingly similar to those the First Circuit held improper in *Lantus*.

The Second Circuit recently followed *Lantus*'s reasoning in a case where a brand manufacturer listed patents claiming methods of treatment using a combination of two active ingredients, even though the relevant NDA product contained only one of those two active ingredients.[65] The Second Circuit concluded that under *Lantus* "[a] patent claim that fails to explicitly include the

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[61] *Id.* at 4, 7.
[62] *Id.* at 5.
[63] *Id.* at 10.
[64] *Id.*
[65] *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd.* (*Actos*), 11 F.4th 118, 127, 134-35 (2d Cir. 2021).

drug actually makes *neither* type of claim on the drug" permitted under the listing provisions.[66]

Teva's other arguments that its patents are properly listed are unavailing. First, Teva contends that the OBTA undermined *Lantus* by adding "component" or "composition" in ways that changed the meaning of § 355.[67] The OBTA did no such thing. Each instance of "component" in § 355 was already included in the statute before OBTA was enacted.[68] And "composition" was added to the listing provisions only to further specify the *limits* on the scope of listable patents—codifying limits that existed in FDA regulations (but not the statute) pre-OBTA.[69]

Second, Teva argues that even though the asserted patents do not claim the drug substance listed in the NDA (albuterol sulfate), or even the drug product listed in the NDA (ProAir HFA Inhalation Aerosol), the Court should find its Orange Book listings proper because "[t]he Listing Statute Broadly Requires Listing All Patents that 'Claim the Drug,'" and the asserted patents purportedly "read on" the ProAir HFA inhaler—meaning that the ProAir HFA's inhaler meets each claim element of at least one claim of the asserted patents.[70] But Teva's

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[66] *Id.* at 134-35 (citing *Lantus*, 950 F.3d at 8).
[67] Teva Br., ECF No. 28, at 13-14 (citing 21 U.S.C. §§ 355(b)(1)(A)(ii), (iii), (v), (viii).
[68] 21 U.S.C.S. §§ 355(b)(1) (LexisNexis 2019); *see also* Amneal Br., ECF No. 48, at 25.
[69] 21 U.S.C. § 355(b)(1)(A)(viii)(I); *cf* 21 C.F.R. § 314.53(b)(1) (2003).
[70] Teva Br., ECF No. 28, at 9, 14-16.

argument ignores the statutory text. Even assuming *arguendo* that the ProAir device can be considered a part of the "drug," under the statutory text, it is not a sufficient condition for proper listing that the patent "claims the drug." The statutory text allows only listing of a patent that "claims the drug . . . *and* is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent," or else claims an approved method of using the drug.[71] Here, Teva's device and device component patents are none of those three types.[72]

Third, Teva argues that "patents claiming drug products *or their components* must be listed in the Orange Book."[73] Teva claims that the definition of "dosage form" in 21 C.F.R. § 314.3 takes into account "such factors" as "[t]he way the product is administered" and "[t]he design features that affect frequency of dosing;" thus, Teva argues, it must list "patents covering any of the components . . . that contribute" to ProAir HFA's "finished dosage form" if they "relat[e] to 'the way the product is administered' and 'design features that affect frequency of dosing.'"[74] According to Teva, these include device and device component patents.

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[71] 21 U.S.C. § 355(b)(1)(A)(viii)(I) (emphasis added).

[72] Teva cites *Apotex*, 347 F.3d at 1343-44 for its dictum that "[t]he listing decision thus requires what amounts to a finding of patent infringement, except that the 'accused product' is the drug that is the subject of the NDA." Teva Br., ECF No. 28, at 21. But that statement only occurred in the Court's analysis of its subject-matter jurisdiction, and in any event is no longer accurate in view of the OBTA amendments to the listing provisions.

[73] Teva Br., ECF No. 28, at 16 (emphasis added).

[74] *Id*. at 16-17.

In the FTC's view, this argument stretches the FDA's guidance well beyond a fair reading. As explained above (at 19), the FDA's guidance on whether to list a "drug product" patent stated the "*key factor* is whether the patent being submitted *claims* the finished dosage form."[75] Teva offers no authority or even explanation for widening the FDA's guidance to allow listing of device or device component patents that "contribute" in some way to the finished dosage form (rather than claiming it), or that "relat[e]" to the factors the FDA uses to determine a drug's dosage form.[76]

Indeed, in *Lantus*, the First Circuit rejected virtually the same argument that Teva now makes. There, Sanofi argued it could list its device component patent—claiming the drive mechanism of an insulin injector pen—because it was required to list patents on "integral components" of the approved drug product.[77] Noting a "gap between [Sanofi's] reading of the law and its filing of a patent that does not claim the listed drug," the First Circuit concluded there was "nothing in the statute or regulations that welcomes such a further expansion of the already stretched statutory terms, whereby an integral part of an injector pen becomes the pen itself, and in turn is a drug."[78] The First Circuit ultimately held that the patent was

[75] 68 Fed. Reg. at 36680 (emphasis added).
[76] Teva Br., ECF No. 28, at 16-17.
[77] *Lantus,* 950 F.3d at 8.
[78] *Id.*

improperly listed because, even "assum[ing] for the sake of argument that the Lantus SoloSTAR is a drug under the statute, there is still a vital link missing: the '864 patent does not claim or even mention the Lantus SoloSTAR."[79] The same logic applies here.[80]

Under Teva's reading of the statute, drug companies could list any patent—and obtain a 30-month stay of FDA approval of a generic competitor—where the patent covers even one minor component of a drug-device combination product. The limits Congress imposed on Orange Book listings reflect a desire to avoid such an absurd result, in which patents on even minor device components trigger a stay of FDA approval and delay competition from less expensive generic drug products. Indeed, Teva's interpretation is inconsistent with the language of the listing provisions and would impermissibly render the "drug substance" category in the

[79] *Id.*

[80] Teva briefly argues that any patent not expressly excluded in the listing regulation may be listed. Teva Br., ECF No. 28, at 17 *quoting* 21 C.F.R. § 314.53(b)(1) ("Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this section, and information on these patents must not be submitted to FDA.") (emphasis omitted). This sweeping argument lacks merit for the reasons identified by Amneal. Amneal Br., ECF No. 48, at 18 n.7. In addition, 21 C.F.R. § 314.53(b) imposes numerous requirements for listing drug substance, drug product, and method-of-use patents that Teva's argument would read out of the regulation by collapsing all of § 314.53(b) into its final sentence. Teva's argument would similarly make redundant the OBTA's adoption of the "drug substance" and "drug product" requirements in 21 U.S.C. § 355(b)(1)(A)(viii)(I).

listing provisions surplusage.[81] Specifically, if any patent on a "component" of the drug product—including the active ingredient—is listable as a drug product patent, then there would be no reason to have a separate "drug substance (active ingredient)" category.[82] The active ingredient is undoubtedly a "component" of the "drug product," along with the inactive ingredients.[83] Thus, the existence of a separate category of "drug substance" for the active ingredient indicates that "drug product" patents are not listable unless they claim the entire drug product, not just components.

In short, the Hatch-Waxman Act does not authorize the listing of the asserted patents because they do not mention any drug in their claims and are therefore not "drug product (formulation or composition) patent[s]" under the listing provisions, as Teva claims.

II. Improper Orange Book Patent Listings Harm Competition

Improper Orange Book listings harm competition by deterring and delaying entry of lower-cost generics. As discussed, the Hatch-Waxman framework gives brand drug manufacturers with patents listed in the Orange Book the ability to

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[81] *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 299 n.1 (2006) (statutory interpretation presumes that "statutes do not contain surplusage").

[82] 21 U.S.C. § 355(b)(1)(A)(viii).

[83] *See Ben Venue Lab. v. Novartis Pharm. Corp.*, 10 F. Supp. 2d 446, 458 (D.N.J. 1998) ("There can therefore be no serious question that, under 21 C.F.R. § 314.53(b), a 'drug substance' or 'active ingredient' may be a 'component' of a drug product . . . .").

initiate patent infringement litigation against would-be generic competitors before the FDA approves their ANDAs, which can lead to a 30-month stay of approval, regardless of whether the patent is properly listable.[84] Purchasers, like patients, hospitals, and health plans, are harmed each day that competition is delayed beyond the point the FDA would have otherwise approved a generic challenger's ANDA product. These potential harms—both in terms of higher drug prices and patient health—are serious.

When generic drugs enter a market, prices tend to fall dramatically. The following graph from an FDA study illustrates the effects of increased competition on generic drug prices relative to the brand drug price before entry.[85] Researchers have found that with robust competition, most drug prices "eventually fall[] to 80–85% below the original brand-name cost."[86]

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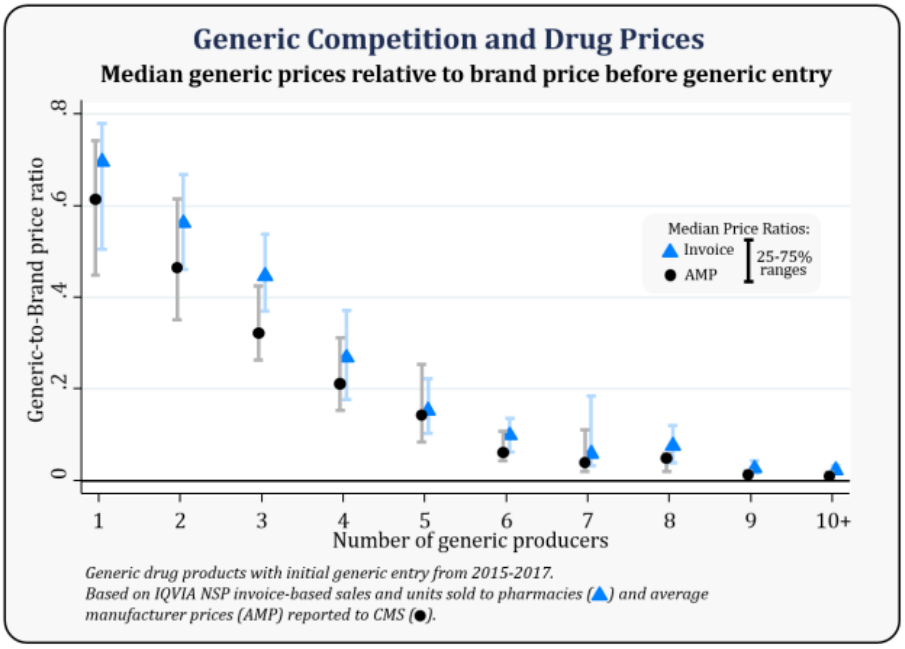
[84] This is true unless the generic competitor prevails in litigation sooner. *But see Lantus*, 950 F.3d at 4 ("[W]hile [the] thirty-month period may be shortened by resolution of the infringement action or order of the court [], the status quo, the allocation of burdens, and the life-span of patent litigation can all work against any such shortening.").

[85] U.S. Food & Drug Admin., Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices 2 (Dec. 2019), https://www.fda.gov/media/133509/download.

[86] Robin Feldman et al., *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 Stan. Tech. L. Rev. 39, 46 (2017); *see also* Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 Ohio St. L.J. 467, 491 (2015) ("[C]ompetition among generics drives prices to the competitive level," which can be "as little as 20% of pre-generic-entry prices.").



In this case, because the asserted patents have been listed in the Orange Book, Teva's suit has triggered the 30-month stay of approval on Amneal's ANDA product until February 2026.[87] If not for this 30-month stay, Amneal alleges the FDA could approve its ANDA product as early as next month, April 2024,[88] and pleads that if approved it could come to market as early as this summer.[89] Absent this Court granting judgment on the pleadings as to counterclaim counts 1–5 and ordering the asserted patents delisted, Amneal's product—and the price competition it would bring—may be delayed by nearly two years.[90]

[87] This is true unless Amneal prevails in this litigation sooner.
[88] Amneal Br., ECF No. 48, at 3.
[89] Amneal Countercl., ECF No. 12 ¶ 122.
[90] The entry of Amneal's product would also increase patient choice.

In addition to raising prices, delayed competition from improper Orange Book listings may in turn harm patient health. In 2018, the American Thoracic Society (ATS) issued a policy statement observing that the high cost of inhalers and other medicines for patients with asthma and COPD has led to higher out-of-pocket expenses and harmed patient health.[91] Based on its review of the academic literature, the ATS concluded that higher out-of-pocket expenses can increase stress, reduce medication adherence, and lead to worse health outcomes, including unnecessary hospitalizations.[92] The ATS also noted that these problems have been "exacerbated by a paucity of generic alternatives"—i.e., by a lack of competition.[93]

Improper Orange Book listings appear to be part of a widespread problem, particularly with inhaler device and device component patents. As explained above, the FTC's Bureau of Competition's November 2023 warning letters disputed over 100 Orange Book listings by ten brand drug manufacturers across 13 inhaler products and four epinephrine injector pens.[94] With respect to even just Teva alone, the letters disputed a total of 42 patent-listings across four inhaler

[91] Minal R. Patel et al., *Improving the Affordability of Prescription Medications for People with Chronic Respiratory Disease: An Official American Thoracic Society Policy Statement*, 198 Amer. J. of Respiratory & Critical Care Med. 1367 (2018).
[92] *Id.* at 1368.
[93] *Id.* at 1367.
[94] *See* FTC Press Release re: Improper Orange Book Listings, *supra* note 10.

products.[95] Additionally, a study published just last year examined all 53 asthma and COPD inhalers approved by the FDA from 1986 to 2020 and found that 39 of these products collectively listed 137 device patents in the Orange Book, the majority of which (105, or 77%) failed to reference an active ingredient.[96]

Further, improper Orange Book listings create barriers to entry that may deter generic competitors from entering the market in the first place. Faced with the prospect of a 30-month delay of FDA-approval, a generic competitor may forgo entry altogether, harming competition.

The revenue generated by brand drug companies from delays in competition caused by improper Orange Book listings and other practices can be significant. A recent academic study of FDA-approved asthma/COPD inhalers calculated the revenue generated by brand manufacturers before and after patents on the active ingredients expired.[97] As illustrated in the graph below, the study found that over

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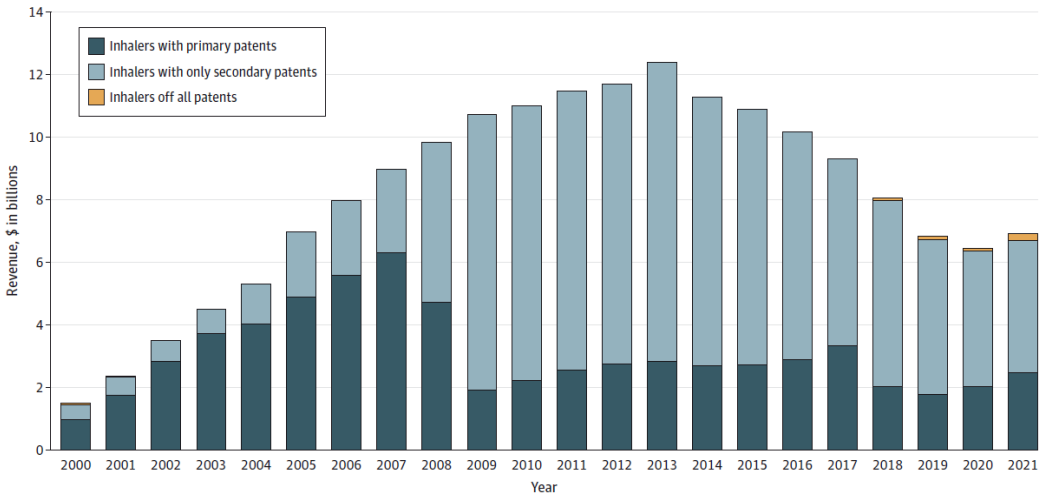
[95] *See* Teva Warning Letter, *supra* note 11; Norton Warning Letter, *supra* note 11.

[96] Brandon J. Demkowicz et al., *Patenting Strategies on Inhaler Delivery Devices*, 164 Chest 450, 452 (2023). This is consistent with a prior study that examined Orange Book patents on asthma/COPD inhalers, epinephrine injectors, and insulin injectors and concluded that 90% of the drug products studied were protected by device patents. *See* Reed F. Beall et al., *Is Patent "Evergreening" Restricting Access to Medicine/Device Combination Products?*, 11 PLOSE ONE 3 (2016).

[97] *See* William B. Feldman et al., *Manufacturer revenue on inhalers after expiration of primary patents, 2000-2021*, 329 J. Amer. Med. Assoc. 1, 3 (2023). This study did not measure the revenue obtained from delays in generic approval specifically due to improper Orange Book listings, but it demonstrates the

the 2000–2021 period, brand manufacturers generated $67.2 billion in revenue while their active ingredient patents were in effect compared with $110.3 billion after the active ingredient patents expired and the inhalers were protected only by later-filed secondary patents, including device and device component patents.[98]

Figure. Revenue Earned in the US on Brand-Name Inhaler Lines Approved by the US Food and Drug Administration, 2000-2021



III. Improper Orange Book Listings May Constitute Illegal Monopolization Under Section 2 of the Sherman Act

Contrary to Teva's arguments in its motion to dismiss, the FTC and courts have long recognized that improper submission of patents for listing in the Orange Book may constitute illegal monopolization—as well as an illegal course of monopolistic conduct—under section 2 of the Sherman Act.[99]

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enormous value for brand drug manufacturers in delaying generic competition through any means—including obtaining 30 month stays through improper listings.

[98] *Id.* at 1.

[99] As the FTC's policy statement explains, improper Orange Book listings are also actionable under section 5 of the FTC Act, which prohibits unfair methods of

Monopolization requires proof of "the willful acquisition or maintenance of [monopoly] power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[100] To establish a section 2 violation, a plaintiff must show "(1) that the defendant possesses monopoly power in the relevant market, and (2) that the defendant has acquired or maintained that power by improper means."[101]

Here, Teva seeks dismissal only with respect to the latter "improper means" element.[102] Demonstrating acquisition or maintenance of monopoly power by improper means requires proof that the defendant has engaged in anticompetitive conduct "to foreclose competition, to gain a competitive advantage, or to destroy a competitor."[103] As described above, improper Orange Book listings can foreclose competition and patient access to affordable medications by enabling brand companies to block generic competition generally for 30 months—regardless of whether the listed patent is valid or infringed by the competitor's product. Moreover, improper Orange Book listings can deter generic drug companies from

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competition. *See* FTC Orange Book Policy Statement, *supra* note 9, at 5-6. There is no federal private right of action to enforce Section 5; this case focuses on Section 2 of the Sherman Act alone.

[100] *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

[101] *Lantus*, 950 F.3d at 7 (quoting *Town of Concord v. Bos. Edison Co.*, 915 F.2d 17, 21 (1st Cir. 1990)) (additional citation and internal quotation omitted).

[102] *See* Teva Br., ECF No. 28, at 24.

[103] *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 482-83 (1992) (quoting *United States v. Griffith*, 334 U.S. 100, 107 (1948)).

entering a market at all, thereby foreclosing competition and depriving patients of lower-priced competing drugs. Courts (and the FTC) have consistently recognized that improperly listing patents in the Orange Book may constitute an improper means of maintaining or acquiring monopoly power—and they have done so both before and after 2003 when Congress enacted the counterclaim for a delisting injunction in 21 U.S.C. § 355(j)(5)(C)(ii).[104]

In this case, Amneal counterclaims that Teva improperly listed the asserted patents in the Orange Book, thus unlawfully maintaining its monopoly power.[105] As described above, these improper listings have enabled Teva to trigger the 30-month stay of approval, effectively delaying entry of Amneal's ANDA product

[104] *See Lantus*, 950 F.3d at 1, 7, 11-15 (reversing dismissal and holding allegations regarding improper listing of device patent could support actionable Sherman Act section 2 claim); *Actos*, 11 F.4th at 134-138 (affirming denial of motion to dismiss and remanding for consideration of whether brand drug manufacturer incorrectly listed patents in Orange Book causing antitrust harm); *Loestrin 24 Fe*, 433 F. Supp. 3d at 315 (ruling "sham Orange Book listing claim" may proceed to jury trial); *In re Gabapentin Pat. Litig.*, 649 F. Supp. 2d 340, 360 n.23 (D.N.J. 2009) (recognizing improper Orange Book listing allegations could support monopolistic scheme allegations); *Remeron*, 335 F. Supp. 2d at 532 (allowing plaintiffs to present facts concerning improper listing in support of monopolistic scheme allegations); Decision & Order, *Biovail*, FTC Dkt. No. C-4060 (settling an action under the antitrust laws against Biovail Corporation for, among other things, wrongful Orange Book listing); FTC Study on Generic Drug Entry Before Patent Expiration, *supra* note 6 at App. H (discussing "three categories of patents that raise Orange Book listability questions"); FTC Orange Book Policy Statement, *supra* note 9.

[105] Amneal Countercl., ECF No. 12 ¶ ¶ 120-25, 134-270.

from as early as this summer to February 2026.[106] These facts, which at the motion to dismiss stage must be accepted, establish a plausible violation of section 2.

IV. The Narrow *Trinko* Exception Does Not Immunize Improper Orange Book Listings From Antitrust Scrutiny

Verizon Commc'ns, Inc. v. Trinko, LLP[107] cannot immunize Teva from antitrust liability for improper Orange Book listings. In *Trinko*, the Supreme Court declined to expand Section 2 of the Sherman Act to capture conduct that was "not a recognized antitrust claim under this Court's existing refusal-to-deal precedents,"[108] particularly where the federal and state regulatory "regime was an effective steward of the antitrust function."[109] The antitrust claims and the regulatory framework at issue here are nothing like those considered in *Trinko*. As explained below, *Trinko* is inapplicable because Amneal's counterclaims are not an expansion of antitrust law, the FDA does not directly police the Orange Book, and the statutory amendment to add a delisting counterclaim does not transform a patent enforcement framework into an antitrust regulatory scheme.

This Court rightly rejected Teva's argument, explaining that "there exists no regulatory scheme [for Orange Book listing] so extensive as to supplant antitrust

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[106] *See supra* Background §§ I, II; Amneal Br., ECF No. 48, at 3; Amneal Countercl., ECF No. 12 ¶¶ 121-22, 130.
[107] 540 U.S. 398 (2004).
[108] *Id*. at 410.
[109] *Id.* at 413.

laws."[110] As Judge Hochberg explained, "[n]o authority has been cited to support the proposition that the antitrust laws have been superseded by the Hatch-Waxman Act or by FDA regulations. *Trinko* does not bar the instant antitrust claims."[111]

First, Amneal does not ask the Court to "recognize an expansion of the contours of §2" beyond existing precedents.[112] Courts have consistently recognized that lawsuits based on improperly listed Orange Book patents may constitute an "improper means" of maintaining or acquiring monopoly power.[113] Even before the Hatch-Waxman Act, courts recognized that improper use of a patent to exclude competitors can violate Section 2.[114]

Second, the FDA's ministerial role in Orange Book listings is nothing like the extensive scheme of Federal Communications Commission (FCC) regulation of telecommunications competition considered in *Trinko*. In *Trinko*, the local phone incumbent, Verizon, allegedly provided poor network access to prospective rivals,

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[110] *Remeron*, 335 F. Supp. 2d at 531.

[111] *Id.* at 531. Other courts have similarly rejected attempts to extend *Trinko* to preclude antitrust claims in other contexts. *See, e.g., Steward Health Care Sys., LLC v. Blue Cross & Blue Shield*, 997 F. Supp. 2d 142, 153 n.6 (D.R.I. 2014) (rejecting argument that "the heavily regulated nature of health care markets makes it improper for courts to intervene on antitrust grounds," explaining "[w]hereas the telecommunications industry at issue in *Trinko* was the subject of extensive antitrust regulation, it cannot be said that the same level of antitrust-focused regulation exists in health care markets").

[112] *Trinko*, 540 U.S. at 412.

[113] *See supra* note 105.

[114] *See, e.g.*, *SmithKline Corp. v. Eli Lilly & Co.,* 575 F.2d 1056, 1065 (3rd Cir. 1978).

leaving them unable to consistently serve the phone customers they sought to take from Verizon. The Telecommunications Act of 1996 "sought to 'uproot' the incumbent [local phone company's] monopoly and to introduce competition in its place."[115] "Central to the scheme of the Act [was] the incumbent [phone company's] obligation … to share its network with competitors," along with "a complex regime for monitoring and enforcement" by the FCC.[116] The New York Public Service Commission imposed similar network sharing conditions.[117] After Verizon's competitors complained about its conduct,[118] New York and the FCC opened parallel investigations; within months, New York issued orders requiring Verizon to pay $10 million to its rivals, and Verizon paid $3 million under an FCC consent decree.[119]

The Supreme Court gave "particular importance" to this "regulatory structure designed to deter and remedy anticompetitive harm" when it declined the *Trinko* plaintiffs' request to expand Section 2.[120] In *Trinko*, the FCC—an agency

[115] *Trinko*, 540 U.S. at 402 (quoting *Verizon Communications Inc. v. FCC*, 535 U.S. 467, 488 (2002)).
[116] *Id.* at 401-02 (citations omitted).
[117] *Id.* at 398.
[118] *Id*. at 403.
[119] *Id.* at 403-04.
[120] *Id.* at 412.

with longstanding competition expertise and statutory enforcement authority[121]—and New York "provided a strong financial incentive for [Verizon's] compliance."[122] When Verizon failed to meet its obligations, the regulators responded quickly, "impos[ing] a substantial fine" and onerous, "*daily* reporting requirements" to ensure compliance.[123] Collectively, this regulatory "regime was an effective steward of the antitrust function."[124]

Here, however, the FDA's "purely ministerial" role with Orange Book patent listings is starkly different from the FCC's role in *Trinko*.[125] "The FDA's mission is to protect the public by ensuring that drugs are safe and effective," not to "resolve economic disputes about the coverage of patent claims."[126] And the

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[121] *See Steward,* 997 F. Supp. 2d at 153 n.6 ("the telecommunications industry at issue in *Trinko* was the subject of extensive antitrust regulation"); *Competition Policy Division, Wireline Competition Bureau*, Fed. Commc'n Comm'n., https://www.fcc.gov/general/competition-policy-division-wireline-competition-bureau (last visited Mar. 20, 2024) ("Our primary mission is to foster competition…"); Judge Douglas Ginsburg & Josh Wright, *Reimagining Antitrust Institutions: A (Modest?) Proposal* (George Mason L. & Econ. Rsch. Paper No. 23-22, at 14, 2023) (forthcoming, Rev. L. Econ.) (explaining "[s]ome sectoral regulators also have sector-specific analogs to the [FTC] Section 5 authority to prevent 'unfair methods of competition.' Agencies with such authority include the FCC, over cable operators…").

[122] *Trinko*, 540 U.S. at 413 (citations omitted).

[123] *Id.*

[124] *Id.*

[125] *Organon*, 293 F. Supp. 2d at 458-59.

[126] *Remeron*, 335 F. Supp. 2d at 531-32 (quoting Fed. Defs.' Mem. in Opp'n to Pls.' Mot. for Prelim. Injunction, *Mylan v. Thompson*, 139 F. Supp. 2d 1 (D.D.C. 2001)).

FDA has stated that it "lack[s] the resources, authority, or expertise to police patent claims" that delay the entry of generic drugs.[127] As the Federal Circuit has explained, the FDA does not "police the listing process by analyzing whether the patents listed by NDA applicants actually claim the subject drugs or applicable methods of using those drugs."[128] The FDA supported the FTC's efforts to scrutinize improper Orange Book patent listings under the antitrust laws.[129]

Nor does the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) create a regulatory structure that supplants the need for the antitrust laws to address anticompetitive harm, as Teva asserts.[130] By its plain terms, the MMA merely provides a mechanism for courts to require delisting of improper Orange Book patents—i.e., an injunctive relief counterclaim—and does not limit or displace the availability of antitrust liability, including for damages.[131]

Specifically, Subclause I of the relevant provision established a counterclaim for an ANDA filer to seek removal of an improperly listed patent from the Orange Book during patent infringement litigation brought under the Hatch-Waxman

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[127] Br. for the U.S. as Amicus Curiae, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844, 2011 WL 3919720, at *17, 27 (U.S. Sept. 6, 2011); *see also Caraco*, 566 U.S. at 424 (noting "the FDA's determination that it cannot police patent claims.").

[128] *Apotex*, 347 F.3d at 1349.

[129] *See* FTC Press Release re: Orange Book Policy Statement, *supra* note 9.

[130] Teva Br., ECF No. 28, at 28.

[131] *See* Amneal Br., ECF No. 48, at 39-40 (quoting H.R. Rep. No. 108-391, at 836 (2003)).

Act.[132] Subclause II specifies that the "claim described in subclause (I)" may only be brought as a counterclaim to a patent infringement suit.[133] Nothing in the statute preempts, or even mentions, the well-established antitrust claims raised by Amneal here—which are claims authorized by the Sherman Act that in no way depend on the authority to bring "the claim described in subclause (I)" of the MMA.

Moreover, the MMA counterclaim does not offer any means to remedy the types of harm to competition from improper Orange Book listings that antitrust liability addresses. For one, the MMA counterclaim cannot lead to monetary damages; it may only correct the Orange Book listing and does not allow for any other remedy.[134] Additionally, the counterclaim arises only if and when a branded drug manufacturer sues a generic drug manufacturer for infringement of a product covered by an Orange Book listing. Thus, the counterclaim cannot address the chilling effect of improper patent listings that discourage would-be competitors from even attempting to enter the market—harming competition and consumers. Such a mechanism does not constitute a comprehensive antitrust regulatory regime.

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[132] 21 U.S.C. § 355(j)(5)(C)(ii)(I) ("If an owner of the patent … brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information...").

[133] 21 U.S.C. § 355(j)(5)(C)(ii)(II) ("Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).").

[134] *See Id*. § 355(j)(5)(C)(ii)(II) (Applicants "not [] entitled to damages").

Indeed, even after the enactment of the MMA counterclaim, courts have repeatedly and consistently recognized that improper Orange Book listings can violate Section 2.[135] The FTC is not aware of any case extending *Trinko* to preclude antitrust liability for improper Orange Book listings. This Court should reject Teva's invitation to become the first. Notably, in a case alleging sham litigation under the Hatch Waxman Act, the Third Circuit rejected a branded drugmaker's *Noerr-Pennington* argument, holding that courts "must not immunize a brand-name manufacturer who uses the Hatch-Waxman Act's automatic, 30-month stay to thwart competition. Doing so would excuse behavior that Congress proscribed in the antitrust laws."[136] Courts have long recognized that antitrust exemptions are "strongly disfavored and have only been found in cases of clear repugnancy between the antitrust and regulatory provisions."[137] No such conflict exists here.

CONCLUSION

For the foregoing reasons, the Court should grant Amneal's motion for a judgment on the pleadings as to counterclaim counts 1-5 and order the asserted patents delisted. The Court should evaluate the issues consistent with the principles

[135] *See supra* note 105.
[136] *AbbVie Inc.*, 976 F.3d at 361.
[137] *Otter Tail Power Co. v. United States*, 410 U.S. 366, 372 (1973).

described above, including that improper Orange Book listings may cause substantial harm to competition and may violate the antitrust laws.

Dated: March 22, 2024

Respectfully submitted,

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Exhibit “S3”

This is Exhibit “S3” referred to in the Affidavit of Emily Seaby, sworn before me this 26th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Jon Wall

Teva's acquisition of Allergan's generic pharmaceuticals business

Position Statement

See the news release that corresponds to this position statement.

OTTAWA, April 18, 2016 — This statement summarizes the approach taken by the Competition Bureau in its review of the proposed transaction between Teva Pharmaceutical Industries Ltd. (Teva) and Allergan plc (Allergan) pursuant to a purchase agreement announced on July 27, 2015 related to the acquisition of Allergan's generic pharmaceutical business. [1]

The Bureau announced on April 4, 2016 that it had reached a consent agreement with Teva, which resolves the competition concerns related to the transaction. Following its review, the Bureau concluded that Teva's acquisition of Allergan'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 due to the elimination of future competition between the parties.

On this page

Background

Teva and Allergan are suppliers of pharmaceutical products in Canada and globally. Teva specializes primarily in generic drugs, and Allergan has a large portfolio of both branded and generic pharmaceuticals. These products include both prescription and over-the-counter medications in finished dose form (i.e., drugs in final form marketed for use).

The Bureau's review focused on whether the transaction was likely to substantially lessen competition in markets where both parties are current suppliers or, in the case where either Teva or Allergan has a product in development for sale in Canada, substantially prevent future competition. The Bureau took into consideration, among other factors, the extent to which effective competitors would remain in the relevant markets after the transaction, and the likelihood of timely entry by other potential suppliers.

In conducting its review, the Bureau cooperated with a number of its international counterparts, including the United States Federal Trade Commission and the European Commission. The Bureau also conducted interviews with numerous stakeholders, including provincial drug formularies, group purchasing organizations, and competitors.

Analysis

Relevant markets

The overlap between Teva and the Allergan business it proposes to acquire relates to portions of their respective portfolios of generic prescription drugs. Generics are determined by Health Canada to be bioequivalent to a brand/reference drug, meaning they contain the same medicinal ingredients and have the same pharmacological effects as their branded counterparts. Generics can be approved for sale in Canada by Health Canada once the

patent or exclusivity period of the corresponding branded drug has expired or been successfully challenged. Generics play a significant role in reducing the price of drugs in Canada. Provincial drug formularies and private drug plans employ automatic substitution rules that result in consumers being supplied with the lower-priced generic equivalents of drugs prescribed by their doctors, unless the doctor specifies that such substitution should not occur.

Consistent with recent pharmaceutical reviews involving generic drugs, the Bureau found that the parties' products should 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. In some instances, it was appropriate to differentiate products based on other factors, such as differences in dosage strength.

The relevant geographic market for the supply of finished dose pharmaceutical products is no broader than Canada. Significant regulatory barriers limit the entry of pharmaceutical products from outside of Canada.

Effective remaining competition

For each relevant market, the Bureau considered whether there were sufficient alternatives to products of the merging parties that constitute effective remaining competition. This analysis consisted primarily of identifying remaining suppliers of equivalent generics to the parties, and any likely future generic suppliers. The Bureau also considered whether the branded drug remained in the market following the entry of generics, as well as the brand's market share relative to the generics.

When assessing potential future suppliers, the Bureau considered factors such as the likelihood, timeliness and effectiveness of entry. Where a drug in development has been approved for sale by Health Canada (i.e., received a Notice of Compliance), this information is publicly available. However, until

such approval has been granted, the information on the status of drug development, including whether approval has been sought from Health Canada and the status of Health Canada's approval process, is confidential. Therefore, in those relevant markets where the Bureau required information to assess future entry where Health Canada approval had not yet been granted, the Bureau relied heavily on information obtained directly from competing drug developers on the status of their drug approval processes and anticipated timing for entry. The Bureau also assessed whether these other developers were likely to be effective competitors by considering factors such as breadth of portfolio, existing sales volumes and customer relationships, and experience obtaining the required regulatory approvals. The Bureau also coordinated extensively with Health Canada, in accordance with our respective confidentiality policies.

Consistent with previous reviews in the pharmaceutical industry, market contacts stated that the entry of the first, second and third generic competitor into a market frequently resulted in lower prices. This is in part a result of regulations that effectively cap the prices of generic drugs, with the prices lowering with the entry of each of the first three generic suppliers.

Remedy

The Bureau identified two products where it concluded the transaction would substantially lessen or prevent competition: tobramycin inhalation solution and buprenorphine/naloxone tablets.

Tobramycin inhalation solution is used for the management of cystic fibrosis in patients with certain chronic pulmonary infections. Teva recently launched a generic version of this product in early 2016, and Allergan is also developing the product. One other potential generic supplier had received Health Canada approval, but the Bureau did not identify a sufficient number of future suppliers that would likely entere the market and become effective

competitors in a timely manner. Tobramycin is also available in other formats, including ophthalmic solution, ophthalmic ointment, and injection. The Bureau found that the inhalation solution represented a distinct product market. Healthcare professionals often decide on the most suitable drug format for a particular patient. Further, generics are generally priced with reference to the historical branded drug price in the same format and dosage strength. Accordingly, the Bureau concluded that the transaction would likely result in a substantial prevention of competition in the supply of tobramycin inhalation solution.

Buprenorphine/naloxone is a tablet used for substitution treatment in adult opioid drug dependence. Teva is a supplier of a generic version of this drug, as is one other generic supplier. Allergan is developing this drug. Allergan was the only other developer identified as likely to enter in a timely manner, and would therefore have been the third generic supplier. The Bureau concluded that the transaction would likely result in a substantial prevention of competition in the supply of buprenorphine/naloxone tablets.

Conclusion

Teva has entered 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. The consent agreement specifies that Teva will determine for each product whether it will sell its own or Allergan’s assets prior to the completion of the sale. Pursuant to the consent agreement, these products must be sold to buyer(s) approved by the Commissioner of Competition. The Bureau is confident that the implementation of the consent agreement will adequately resolve its concerns arising from the merger with respect to these two products.

The Competition Bureau, as an independent law enforcement agency, ensures that Canadian businesses and consumers prosper in a competitive and innovative marketplace.

This publication is not a legal document. The Bureau's findings, as reflected in this Position Statement, are not findings of fact or law that have been tested before a tribunal or court. Further, the contents of this Position Statement do not indicate findings of unlawful conduct by any party.

However, in an effort to further enhance its communication and transparency with stakeholders, the Bureau may publicly communicate the results of certain investigations, inquiries and merger reviews by way of a Position Statement. In the case of a merger review, Position Statements briefly describe the Bureau's analysis of a particular proposed transaction and summarize its main findings. The Bureau also publishes Position Statements summarizing the results of certain investigations, inquiries and reviews conducted under the *Competition Act*. Readers should exercise caution in interpreting the Bureau's assessment. Enforcement decisions are made on a case-by-case basis and the conclusions discussed in the Position Statement are specific to the present matter and are not binding on the Commissioner of Competition.

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Footnote

1 Analytical methodologies are applied, and enforcement decisions are made, on a case-by-case basis. The methodologies and conclusions discussed in this statement are specific to the review of the transaction in question and are not binding on the Commissioner. The legal requirements of section 29 of the *Competition Act*, and the Bureau's policies and practices regarding the treatment of confidential information, limit the Bureau's ability to disclose information obtained during the course of a merger review.

Date modified:

2022-01-20

ontact the Competition Bureau

Exhibit “S4”

This is Exhibit “S4” referred to in the Affidavit of Emily Seaby, sworn before me this 26th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Jon Wall

Generic Drug Sector Study

Report

October 29, 2007

PDF version

Generic Drug Sector Study

521 KB (kilobytes), 66 Pages

Executive summary

The Competition Bureau promotes and protects competitive markets across the entire economy. The Bureau is not only responsible for enforcing the civil and criminal provisions of the *Competition Act*, it is also responsible for advocating for greater reliance on market forces to deliver the benefits of ompetition to Canadians.

Canada's health system is an area where competition is often viewed as playing a limited role. The reality is that competitivemarkets are responsible for delivering many of the products and services on which our health system relies. Given their importance to the welfare of Canadians and because this is a large market — at approximately 10% of GDP (Gross domestic product), health related markets have been a key enforcement and advocacy priority for the Bureau for several years.

The Bureau's health-related advocacy activity has focused on pharmaceuticals. This reflects the role of pharmaceuticals in treating patients and their importance as a source of health care costs — at $17.8 billion in 2006, they are the second largest source of health care costs. The Bureau has specifically focused its attention on prescribed generic pharmaceuticals. Generics play an important role in keeping health costs down by providing competition for brand drugs when they lose patent protection.

Several studies have found prescription generics to be relatively more expensive in Canada than in other countries. Thestudies prompted the Bureau to conduct the generic drug sector study to examine the generic drug market and identify areas where changes in the market framework may secure greater benefits through competition.

In conducting the study, the Bureau relied on publicly available information, data purchased from data providers, and information voluntarily provided by sector participants. In July 2007, a preliminary draft of the study was circulated to key interest groups for fact-checking and to provide them with an opportunity to offer additional information.

Key findings in the study include the following:

- Generic drugs are supplied through a unique and complexframework. Physicians prescribe medication to be taken by patients.In filling the prescription, pharmacies can supply any brand-name orgeneric drug product listed on formularies (or drug plan productlists) as interchangeable for the prescribed medication. Drugs arepaid for by drug insurance plans or out-of-pocket by consumers.Government and private drug plans provide coverage for approximately98% of all Canadians. Pharmacies are normally paid the invoice price.
- Generic manufacturing has become more competitive over thepast 15 years. It appears that strong competition exists in thesupply of many generic drugs in Canada. The end of patent protectionfor a drug can now lead to supply within a short period of manyinterchangeable generic products.

- In most provinces, an important way in which manufacturerscompete to have their product stocked by pharmacies is by offeringthem rebates off invoice prices. Rebates provide incentive forpharmacies to select a particular manufacturer's product. It has notbeen possible to obtain detailed evidence regarding the size of theserebates. Public sources and information provided by partiesinterviewed for this study estimate these to be 40 per cent of theprice the pharmacy is invoiced. Rebates are currently prohibited intwo provinces, Ontario and Quebec. However, legislation adopted inOntario in 2006, and under consideration in Quebec, allows genericdrug manufacturers to provide professional allowances to pharmacies.
- Competition by generic manufacturers to offer lower pricesthrough rebates is not reflected in prices paid by either public orprivate plans, or out of pocket. Rather, until recently, prices paidfor generic drugs across the country tended to reflect the maximumgeneric drug prices allowed under Ontario's drug plan. This changedin 2006 when Ontario reduced the maximum it would pay for genericdrugs to 50% of the brand-name product price. These lower prices arenot paid by private drug plans in Ontario, or drug plans in otherprovinces, although this pricing discipline is due to be adopted inQuebec in 2008.
- Plans incorporate various policies, such as maximum genericprices and so-called "most favoured nation" clauses, toreduce their generic drug costs. However, these policies providelimited incentive for manufacturers to compete by offeringcompetitive generic prices to the plans.

A regulatory and market framework where incentives to supplydrug plans more closely reflect the underlying market dynamics couldprovide significant benefits to drug plans, and in turn to insurers,employers and Canadians.

The Competition Bureau will continue its work in the genericdrug sector by examining possible options for obtaining the benefitsfrom competition and the impediments to their adoption. Measures foraccomplishing this goal may include, for example:

- providing manufacturers with incentives to compete to belisted on plan formularies;
- using competitive tendering processes to determine theproducts that can be dispensed by pharmacies;
- monitoring of the net price paid by pharmacies for genericdrugs to ensure the price paid by plans reflects competitive prices;and,
- an increased role for private plans in obtaining lower pricesfor their customers.

Table of contents

Appendices

List of tables

List of charts

1. Introduction

The development and supply of pharmaceuticals is an important part of health care delivery in Canada. Pharmaceuticals are the second largest and fastest growing source of health care costs in Canada. In 2006, they accounted for an estimated 17% of all health care spending in the country. [1] Total retail and hospital expenditures on pharmaceuticals (at invoice cost) in 2006 were $17.8 billion. [2]

Generic pharmaceuticals (“generics”) play an important part in helping to control prescription drug costs in Canada. Generics are determined by Health Canada to be “bio-equivalent” to patented pharmaceuticals. Their role is to provide competition for brand-name products when their patent protection ends.

Generics account for a large and growing portion of pharmaceuticals dispensed in Canada. Their share of prescriptions dispensed through retail pharmacies in 2005 was 43%. In 2005, total generic drug spending was $3.2 billion, with an annual growth rate of 13.6%. From 2004 to 2005, retail purchases of generic drugs grew at 12.1%, twice the growth of brand-name drugs. Generic drugs captured a smaller share of hospital spending at 11.6% in 2005, but were 36.4% higher than in 2004, four times the growth rate for brand-name drugs. [3]

The benefits of generics are indicated by their share of pharmaceuticals costs relative to their share of prescriptions. While accounting for 43% of drug prescriptions in 2005, they accounted for only 18% of drug expenditures. [4] As discussed later in the report, generic retail drug prices are frequently significantly lower than the corresponding bio-equivalent brand-name product prices.

Despite these savings, there is widespread concern in Canada that generics are not providing the benefits they could. A series of studies have found Canadian pharmacy invoice prices for generic drugs, which generally reflect the amount reimbursed by public and private drug plans, to be on average substantially higher than in othercountries. For example, the June 2006 report on generic prices by thePatented Medicines Price Review Board (PBPRB) concludedthat Canadian retail pharmacy invoice prices for generic drugs aresubstantially higher than in 10 of the 11 comparator countriesconsidered. [5]The PBPRB (Patented Medicines Price Review Board)estimated that Canadian non-patented prescription drug spending couldhave been reduced by as much as 32.5%, or $1.47 billion in 2005, ifCanadian retail pharmacy prices were the same as the correspondinginternational median prices. [6] Acting on these concerns,provincial and federal governments in Canada have taken, or areconsidering, a number of actions to reduce their generic drug costs.

Generic drugs are an important area of interest under the NationalPharmaceutical Strategy (NPS). The NPS is part of the 10Year Plan to Strengthen Health Care agreed to by First Ministers onSeptember 16, 2004. [7] Under the NPS, in October 2005,the PBPRB (Patented Medicines Price Review Board)was given responsibility to monitor and report on non-patentedprescription drugs. [8] Among the nine elements ofthe NPS (National Pharmaceutical Strategy) are theacceleration of access to non-patented drugs and the achievement ofinternational parity on generic drug pricing. [9]

Provincial governments are also acting individually to reduce theirgeneric drug costs. In June 2006, the Ontario government amendedlegislation to require that generic drugs reimbursed under provincialdrug plans normally be priced at no more than 50% of their brand-namereference product. [10] Previously, maximum pricesfor the first generic in Ontario were set at 70% of the brandedequivalent, with subsequent generics having a maximum price of 90% ofthe first generic. In February 2007, Quebec adopted a new policylimiting the price of the first generic drug to 60% of the price ofthe brand-name drug and subsequent generics to 54% of the brand-namedrug. [11]

While there is widespread concern regarding the supply andpricing of generic drugs in Canada, there is substantial uncertaintyabout the underlying causes for the findings of high Canadian prices.Potential explanations include the following:

- The use of inappropriate statistical methodologies [12]
- Higher domestic concentration of the generic manufacturingindustry
- Provincial and federal government regulatory practices
- Provincial pharmaceutical reimbursement practices.

Assessing these and other possible reasons for the performanceof the Canadian generic drug sector requires an understanding of theunderlying competitive framework. This framework involves a complexinterplay of:

- Provincial and federal legislation and regulation
- Domestic and foreign generic drug manufacturers and suppliers
- Distributors
- Pharmacy benefit managers
- Rural, banner, mass merchandise and other pharmacies
- Provincial, federal and private insurance plans.

While studies have been done concerning separate elements ofthis framework, the interplay between the various elements has notbeen systematically examined.

Bureau purpose and interest in conducting the generic drug sector study

The Competition Bureau, under the direction of the Commissioner ofCompetition, is responsible for the administration and enforcement ofthe *Competition Ac*, a federal statute that applies to allsectors of the Canadian economy. The Commissioner is also responsiblefor the administration and enforcement of the *ConsumerPackaging and Labelling Act*, the *Textile Labelling Act* andthe *Precious Metals Marking Act.* The purpose of the *CompetitionAct*, as set out in section 1.1, is to maintain and encouragecompetition in Canada in order to promote the efficiency of theCanadian economy and provide consumers with competitive prices andproduct choices.

The Act defines a number of practices that are prohibited ascriminal offences or are subject to review by the Competition Tribunalunder the civil provisions of the Act. The Act does not provide theBureau with any authority to decide the law or to compel business toadopt any particular type of conduct. Further information is availableon the Bureau website, at www.competitionbureau.gc.ca.

The Bureau promotes competition in two ways.

- It is a law enforcement agency. It investigates allegationsof anti-competitive conduct and pursues criminal and civil remediesto stop anti-competitive behaviour.
- It also acts as an advocate for competition. To that end, itfrequently makes submissions to legislative bodies or regulators onhow to implement reforms that encourage competition.

In its advocacy role, the Bureau strives to ensure thatcompetitive factors are taken into consideration in the formulation ofpolicies. It advocates that regulators and policy makers rely onmarket forces to achieve the benefits of competition, namely lowerprices, better quality and improved product choice for Canadians.Given the important benefits of competition, regulation should onlyinterfere with market forces where necessary, and then, only to theminimum extent needed to achieve other policy objectives.

The Bureau's interest in conducting the current study comes fromits advocacy role. The intent of the study is to outline and describethe competitive framework for prescribed generic drugs in Canada, witha focus on market structure and regulatory features.

The purpose of this study is not to examine Canadian genericdrug prices relative to other countries. Rather, it is to provide anunderstanding of the underlying competitive framework in order toidentify potential areas for further promoting the benefits ofcompetition. These areas will provide the basis for further Bureauanalysis and advocacy work on generic drugs.

In conducting this study, the Bureau relied on publiclyavailable information as well as information provided voluntarilythrough extensive interviews and contacts with industry participantsfrom the private and public sectors. The Bureau would like to thankall parties that have provided information for the study.

Organization of the report

The competitive framework for generic drugs involves a complexset of interactions between manufacturers, distributors, drugdispensers (pharmacies and hospitals) and payers or reimbursers(public and private drug plans and patients). This report outlines keyfeatures and roles of industry participants at each level related togeneric drug competition.

Chapter 2 examines generic drug manufacturing in Canada. Chapter 3discusses the role of independent pharmacywholesalers and distributors(IPD (Independent Pharmacy Distributors)). Chapter4 addresses the practices of dispensers of generic drugs. Section Aconsiders retail pharmacies, section B deals with hospital pharmacies.Chapter 5 examines key features of the reimbursement framework forgeneric drugs. Public drug plans, the largest source of retailprescription drug funding in Canada, are considered in Section A. Therole of private insurers is examined in Section B. Chapter 6provides a summary of key findings.

2. Canadian generic drug manufacturing

Section 2.1 of this Chapter describes the Canadian generic drugmanufacturing sector. Section 2.2 outlines the considerationsmanufacturers take into account in determining whether to supply aparticular generic drug. Section 2.3 discusses the barriers to entryinto the supply of a generic drug. Section 2.4 examines the dimensionsfor

competition among generic manufacturers. Finally, section 2.5considers the state of manufacturing competition in Canada.

2.1 Manufacturing description

There are over 15 suppliers of generic drugs in the country with 13companies having manufacturing facilities in Canada. The largestCanadian manufacturer, Apotex, is domestically owned and controlled. [13] Of the next nine largest suppliers, seven have a parent company orgroup that is foreign-based.

The larger manufacturers tend to offer a large portfolio ofdrugs across multiple therapeutic classes and in a variety of forms,while others are less diversified or more specialized. For example,Taro Pharmaceuticals, an Israeli pharmaceutical company entered theCanadian market in 1984 and specializes in topical products. Hospira,a 2005 entrant, specializes in products used in hospitals includingcritical care products and specialty injectable pharmaceuticals.Sandoz acquired Sabex in 2004, and it specializes in injectable andophthalmic generic pharmaceutical products.

Table 1. Shows the ranking of generic manufacturers based on the value of their sales to hospitals and retail pharmacies in Canada

2006 Rank	Manufacturer	Year 2006 $(000s)	Year 2006 (%)	Year 2006 Cumulative (%)
1	Apotex	1,100.8	34.16	34.16
2	Novopharm	483.0	14.99	49.15
3	Genpharm [14]	365.3	11.34	60.48
4	Ratiopharm	359.5	11.16	71.64
5	Pharmascience	280.5	8.70	80.34
6	Sandoz Canada	190.1	5.90	86.24
7	Cobalt Pharma	77.4	2.40	88.65
8	Mayne Pharma Canada [15]	54.8	1.70	90.35
9	Taro Pharmaceuticals [16]	37.3	1.16	91.50
10	Ranbaxy Pharmaceuticals Canada	34.2	1.06	92.56
11	Laboratoires Riva	28.2	0.88	93.44
12	Nu-Pharm	14.8	0.46	93.90
13	Hospira	14.3	0.44	94.34
14	Dominion Pharmacal	12.5	0.39	94.73

Source: IMS (Intercontinental Medical Statistics) Health.

2006 Rank	Manufacturer	Year 2006 $(000s)	Year 2006 (%)	Year 2006 Cumulative (%)
15	ProDoc	11.6	0.36	95.09
	Others	158.2	4.91	100.00
	All Manufacturers	**3,222.5**	**100.0**	
Source: IMS (Intercontinental Medical Statistics) Health.				

Generic manufacturers provide their products through three main supplyroutes: Independent pharmacy distrubutors (IPD), pharmacy chainself distributors, and direct to pharmacy shipments. IPD, discussed inthe next chapter, are the principal supply route followed by selfdistribution. Some direct sales continue to occur but are a decliningmeans for providing supply.

2.2. Generic drug supply considerations

Manufacturers consider several factors when determining whether or notto develop and introduce an independent generic (IG) product. Key considerationsinclude the following:

- Demand size and competition: The projected aggregate demandsize of the reference brand product as well as the relatedtherapeutic class, play important roles. First, the genericmanufacturers take into consideration how many manufacturers areexpected to introduce competing generic versions (independently orunder licensing agreements) of the targeted molecule. Second, brandedcompanies may in some cases provide added competition to the genericmanufacturer by introducing: (i) a competing drug within the sametherapeutic class, or (ii) brand extensions to replace olderformulations whose patents are about to expire. Brand extensions mayreduce the potential demand size available to the generic industryonce the original drug loses patent protection, with a proportion ofpatients being prescribed the new version. [17]
- Development and approval costs: An important part of theentry decision is the evaluation of the total costs of introducing ageneric drug to the market. These costs relate to drug development,the need to conduct bio-equivalence and/or clinical studies andfederal and provincial approvals.
- Timing: The length of time it would take to develop theproduct and obtain approval from Health Canada is a crucialconsideration. This is especially so if it results in the laterelease of a generic product after the relevant brand-name productloses patent protection. [18]
- Specialization and product portfolio: For example, amanufacturer involved in some related work, or specializing in drugswithin a certain therapeutic class or in certain dosage forms(creams, ointments, injectables), would benefit from economies ofscale or scope in production. On the other hand, manufacturers maywish to supply a drug to make their product portfolio more attractiveto customers.
- Legal challenge costs: Challenging brand patents, asdiscussed below, can be a costly and time-consuming process. Ageneric manufacturer already involved in legal challenges may decidenot to enter into another challenge.

Once all factors and risks are considered, the manufacturer isthen in a position to calculate its projected sales versus costs. Ifthe expected return on investment is favourable, then the decision todevelop the product may go forward. There is no unique entry thresholdfor molecules coming off patent. It varies among manufacturers anddepends on the characteristics of the molecule, the manufacturer andthe barriers to entry.

2.3 Barriers to entering the supply of a generic product

Generics may be classified into IG (Independent Generic)s,developed and supplied without authorization by the brand drugmanufacturer, and authorized generics (AG) that aresupplied under licenses granted by the relevant brand drug company. [19] In bringing an IG (Independent Generic) to themarket, a manufacturer encounters various barriers to entry. Keybarriers to entry relate to sunk costs associated with drugdevelopment, regulatory approval and provincial formulary listings. [20]

Drug development

The development of IG (Independent Generic)snormally involves three key steps:

i. Securing the active pharmaceutical ingredient (API): Described bysome as the "key to the industry", an API can be obtainedthrough two sources: (a) international suppliers from India, Chinaand other countries operating in Canada; or (b) internal sourcingthrough integrated arms of the manufacturer.

ii. Pre-Formulation: At this stage, generic manufacturers engagetheir chemists to develop drug formulations based on an analysis ofthe product itself as well as its monograph (listing both the activeand non-active ingredients).

iii. Formulation: This stage involves continuing research anddevelopment (R&D (Research and Development))and the actual preparation of test batches of generic versions, firstin the laboratory (initial small batches) and then in themanufacturing facilities (pilot batches).

The development costs of an IG (Independent Generic)may not be specific to the sale of the product in any particularcountry. Generic products developed and manufactured in one countrycan be supplied to other countries, provided they meet the othercountries' specific regulatory requirements for approval.

Those contacted for this study indicated that development costsfor a generic product can vary greatly from one to the next. Even insimple cases, costs may be around $1.5 million. However, they can beseveral times higher for more complicated products, such as biologics.

Regulatory approval

In order to market an IG in Canada, a manufacturer must obtain approval from Health Canada under the Patented Medicines (Notice of Compliance) Regulations (NOC Regulations). The NOC Regulations, as explained in detail in Appendix 1, address two issues, first, whether the IGis bio-equivalent to the Canadian brand reference product, and, second, whether the IG infringes any valid patents.

Bio-equivalency

To market an IG, the manufacturer must file an Abbreviated New Drug Submission (ANDS) with the Therapeutic Products Directorate (TPD) of Health Canada, containing data that demonstrate the drug'sbio-equivalence with a Canadian reference brand product.

The ANDS must contain sufficient information for Health Canada to assess the bio-equivalence of the generic to the brand-name product, as well as evidence of tests conducted on potency, purity and stability of the new drug. [21]

Standard bio-equivalence studies measure the rate and extent ofabsorption — or bio-availability — of a generic drug. This is thencompared to the same characteristics of the reference drug product.The bio-availability of the generic drug must fall within anacceptable range of the bio-availability of the reference product.According to those contacted for this study, typical costs for conducting bio-equivalency studies are in the range of $1-1.5 millionper product.

In the case of generic drugs, clinical trials are generallyrequired for:

- More complex formulations
- When a brand-name product is claimed to be'process-dependent'
- When a blood-sample study is inappropriate.

For example, topical products do not enter the blood stream sothey are tested through clinical trials.

Clinical trials are research programs conducted to evaluate anew medical treatment, drug or device. These studies involve patientsin the testing of treatments and therapies. Clinical trials, measure adrug's safety, effectiveness, dosage requirements and side effects.They are normally much more costly and time-consuming thanbio-equivalence studies.

In doing its assessment of the bio-equivalence of a generic product(or an NDS), Health Canada relies on dataprovided by the brand-name firm at the time it applied for a Notice ofCompliance (NOC) for itsproduct. These data are subject to a minimum period of protection fromthe date the reference product received its approval from HealthCanada to be marketed. This period of protection, originally fiveyears, was lengthened to eight years under amendments to the NOCRegulations in 2006. Where it extends beyond the life of the patent,the extended period of data protection may create an additional delayin bringing the generic drug to the market. The new regulations alsoallow six added months of data protection for drugs that have been thesubject of clinical trials in children.

Once the NDS is filed and, when applicable, the period of data protection ends, Health Canada typically takes between 12 and 18 months to complete its review. [22]

After filing an NDS (Abbreviated New Drug Submission) with the Minister, generic manufacturers are required under the NOC (Notice of Compliance)Regulations to serve a Notice of Allegation (NOA (Notice of Allegation)) on the patentee that the generic product will not infringe any patent rights. The patentee maythen apply to the court for an order prohibiting the Minister of Health from issuing an NOC (Notice of Compliance) on the basis that one of its patents is being infringed. In such cases, the Minister cannot issue an NOC (Notice of Compliance) until 24 months have passed or the application has been dismissed. Therefore, the patentee can prevent a generic product from entering the market for up to 24 months, simply by alleging that its patents have been infringed.

Prior to 2006, generics were required to address all patents added by the patentee to the Patent Register with respect to the reference drug product. In 2006, the NOC (Notice of Compliance) Regulations were amended to restrict the ability of a drug innovatorto prevent a generic from getting an NOC by adding patents to the patent register after the generic manufacturer files an ANDS (Abbreviated New Drug Submission). [23] The generic now only has toaddress patents that were listed on the register in respect of the reference drug prior to the filing date of the NDS (New Drug Submission). [24]

If a patentee obtains a stay preventing the Minister from issuing an NOC, but the patents relied upon are later found to be invalid or not infringed, the generic firm that was kept off the market may seek damages for itslosses. Under s. (section) 8 of the NOC (Notice of Compliance) Regulations, the court may make any order for relief by way ofdamages that the circumstances require. [25]

In addition to the NOC (Notice of Compliance) Regulations, in some cases, the patentee may rely on a patent lawsuit to prevent entry of a generic drug or to recover damages. In such cases, a generic might succeed under the NOC (Notice of Compliance) Regulations, market the drug and then be sued by the brand-name manufacturer for

patent infringement. In this case, if the brand-name manufacturer is successful, the generic would likely be required to pay damages to the patentee. Conversely, a generic manufacturer may challenge the validity of a patent under the *Patent Act* if it is preventing the company from receiving a NOC (Notice of Compliance).

Success in the NOC (Notice of Compliance) proceedings by a particular firm does not automatically create free entry for all generic firms. Other generic firms still have to obtain an NOC (Notice of Compliance), and address any patents on the Patent Register. Subsequent generic firms may, however, make the same arguments in litigation as the first successful generic. In some cases, the patentee may stop contesting these NOC (Notice of Compliance) cases.

Those interviewed for this study, while not providing related data, indicated that patent challenges under the NOC (Notice of Compliance) Regulations are commonly encountered and are a normal part of bringing an IG (Independent Generic) to market. Legal costs for the first generic to challenge were said to becommonly in excess of $1 million and potentially much higher incomplicated cases. However, the costs for subsequent generic manufacturers, for the same reference product, can be as low as a few thousand dollars when NOA (Notice of Allegation) are no longer being challenged.

Provincial formulary listing

Once an NOC is issued,a product can be sold anywhere in Canada. However, in order to bereimbursed under provincial drug programs and obtain significant salesvolumes the generic product must be listed on provincial formularies.For an IG (Independent Generic), the formularylisting process can take several months from the time an NOC is issued.

In sum, from the time a decision is made to produce a genericdrug, manufacturers typically require between three to six years tobring the product to market. While costs can vary widely from case tocase, they can be in the range of $3.5 million (including costs forbio-equivalence studies, development and regulatory approval) even fora relatively non-complex product.

These costs may be lower where, for example, patent challengesare not encountered or product development costs can be spread acrosssales in countries other than Canada. On the other hand, they can bemuch higher when product development is more complicated, clinicaltrials are required, or relatively high patent challenge costs areencountered. For example, the costs for the development ofbio-generics can be as high as $25 to $50 million. Industry sourceshave indicated that it may take as long as three years after a genericproduct is introduced to market before it will break even, recoupingits sunk developmental and approval costs.

2.4 Competitive dimensions

Competition between generic manufacturers takes place in a number ofdimensions. The key ones are: timing to market, patent challenges,pricing, AG (Authorized (or licensed) Generics) and breadth of product line.

Timing to market

Those contacted for this study cited timing to market as being akey dimension of generic competition. Pharmacies are less likely toswitch to a new generic product if they already have one or twoversions in stock. Stocking multiple manufacturers of the samemolecule is cumbersome and inefficient. For this reason, "timingis of the essence" in the generic drug industry. Productdevelopment and approval is carefully planned to maximize thelikelihood of having a generic version ready as soon as a brand-nameproduct loses patent protection.

The advantage of being first to market is supported by analysisperformed on molecules that lost patent protection and encounteredgeneric entry between January 1998 and December 2006. As shown inTable 2, for about two thirds of the molecules, the first entrant wasable to maintain the leader's position at the end of 2006.

Table 2. Status of the first generic entrant

	Number of Molecules	Percentage
First generic entrant stayedfirst	49	65.3
First generic dropped to 2nd position	14	18.6
First generic dropped to 3rd position	6	8.0
First generic dropped to 4th position or lower	6	8.0
Total	75	100.0

Data source: IMS (Intercontinental Medical Statistics)Health.

Patent challenges

A competitive dimension related to timing to market is companies'patent challenge strategies. A generic company may file its NDS to market a generic becausethe brand-name drug's main patent has expired or is about to expire.By marketing the generic, the generic company is not infringing on anyof the other patents that are held by the brand-name company. [26] However, sources contacted for the study indicated that genericcompanies commonly enter the market prior to the expiry of all listedpatents based on the belief that any remaining brand company patentsare invalid or would not be infringed.

Companies that are the first to file a challenge may gain an advantageover others by getting their product into the supply chain earlier.However, not all generic manufacturers aggressively pursue legalchallenges. According to industry sources, some generic manufacturerschallenge only those patents where there is a perceived certainty of apositive outcome, such as where a brand company is no longerchallenging NOA (Notice of Allegation)s. They mayavoid the costs of legal proceedings altogether by timing their entryto the market in line with the brand's patent expiration.

While a generic that first successfully challenges brand patentsmay have the advantage of being first to market, this can be a costlyprocess. The generic manufacturer has to evaluate whether costs sunkinto a patent challenge can be recouped after the product launches.

In cases where the brand manufacturer fights the first genericchallenger but gives up further challenges, thereby opening the marketto all generics, the first generic challenger may not obtain a majorfirst mover advantage. The generic may be in a situation where it isout of pocket for legal costs and has to compete against othergenerics, IG (Independent Generic)s or AG, which did notincur the same costs. [27]

Pricing

In the case of sales to retail pharmacies, pricing decisions bymanufacturers consist of two elements: the establishment of theproduct's invoice price and the net pharmacy price. The net pharmacyprice is the price paid by the pharmacy net of any off invoice rebatesand discounts. Invoice prices are the amounts typically reimbursed bypublic and private drug plans. As developed further in section 5.A.,limited competition appears to take place in invoice prices. Untilrecently, invoice prices have tended to reflect maximum generic pricesallowed under Ontario

legislation. Price competition amongmanufacturers has tended to take place at the pharmacy level in the form of lower net pharmacy prices. Once generic versions of brand-nameproducts are placed on provincial formularies and are designated asinterchangeable, they essentially become commodity products. [28]

This situation results in pharmacies being the most important andinfluential customers of generic manufacturers. Traditionally, themost important factor in competing for pharmacies' business, wherethere are multiple generics available, has been generic manufacturersproviding rebates off invoice prices. [29]Rebates on generic drugs arenot recorded on invoices, but are provided to pharmacies and hospitalsin a separate transaction often as a lump sum for drugs purchased in agiven period.

It has not been possible to obtain information about the precise sizeand nature of rebates from manufacturers to retail pharmacies andhospitals. Average rebates have been estimated to be 40%, althoughsources indicated they may have been higher. [30] Sources further indicatedthat rebates have been as high as 80% for individual generic products.

The traditional role of rebates as a competitive dimension is beingaltered by the Ontario Transparent Drug System for PatientsAct, 2006, discussed further in Section 4.A.2. The legislationprohibits the granting of rebates to pharmacies. While it allowsprofessional allowances to be provided as a possible alternative torebates, these are capped at 20% of pharmacies' costs for drugsdispensed under Ontario Drug Benefit (ODB) programs. In addition, thelegislation, with certain exceptions, reduces the maximum amount thatcan be reimbursed for generics, under ODB plans, to 50% of the branddrug price. These generic drug price or professional allowance caps donot apply to drugs dispensed under private drug plans. The legislationmakes Ontario the second province in Canada to prohibit rebates. Suchrebates have been prohibited for several years in Quebec and have beenrecently the subject of a number of legal actions. [13]

While the full effects of the Ontario legislation are to bedetermined, the capping of generic drug professional allowances limitsa key dimension of competition among generic drug manufacturers. Thealtered competitive framework may be particularly problematic forgeneric drug manufacturers with limited product portfolios. Theability to grant higher rebates or allowances can provide them a meansto enter and expand market share in competition against rivals withbroader product lines. With rebates and allowances being restricted orprohibited, it can be anticipated that competition in other areas,such as breadth of product line, will assume greater importance.

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Authorized generics

AG (Authorized (or licensed) Generics) are theactual brand-name drug product manufactured by the brand company, butsold as a generic by a licensee or subsidiary of the brand, competingwith independent generics. [32] Because they are identicalto the branded drugs and approved by the patent holder, AG do not encounterthe product development and federal regulatory approval barriers toentry that apply to IG (Independent Generic)s.Although in some provinces listing of AG on provincialdrug formularies can be faster, under the streamlined formularylisting process employed by most provinces there is no advantage for AG.

Introducing an AG (Authorized (or licensed) Generics)prior to the expiration of a brand-name product's period of patentprotection runs counter to the business interests of a brand-namemanufacturer. The lower-price AG will simply erodethe market share of its higher priced brand-name counterpartdiminishing the brand company's revenues. However, licensing thesupply of an AG (Authorized (or licensed) Generics)after the end of patent protection potentially provides the brandcompany a means to make some returns on a portion of generic drugsales.

A brand-name manufacturer may decide to license the manufacturing anddistribution of the AG (Authorized (or licensed) Generics)to an IG (Independent Generic) manufacturer. Thedecision of an IG (Independent Generic)manufacturer to partner with a brand-name manufacturer for the releaseof an AG (Authorized (or licensed) Generics) isbased on several factors. These may include their ability to source APIs to produce theirown generic version and the expected return on supply of the AG versus developingand marketing its own IG (Independent Generic). IG manufacturers differ on their AG strategies. Whilesome engage in little if any supply of AG, othersincorporate them as a component of their business strategy. Accordingto industry sources, the number of AG available in theCanadian market has been trending downwards. In 2006, AG accounted foronly about 7% of the generic sales, compared to about 15% in the early90s.

An issue about introducing an AG (Authorized (or licensed) Generics) is that it may affect the incentive for a generic manufacturer to develop an IG (Independent Generic). [33] This is unlikely to be an issue for drugs having high sales relative to entry costs. However, it has the potential to affect the entry of IG (Independent Generic)s for drugs having relatively smaller valued sales. This may be particularly significant when the AG (Authorized (or licensed) Generics) is able to obtain a first mover advantage. This matter is considered in Table 3.

Statistical analysis was performed on a set of molecules that lostpatent protection between 2001 and 2006 and where the first genericcompetitor entered within the period. An AG entered 26 (36%)of the 75 drug markets in the sample. [34] No clear pattern was foundof AG (Authorized (or licensed) Generics) enteringfirst. Of the 26 markets in which both an AG (Authorized (or licensed) Generics) and an IG (Independent Generic) entered, the IG (Independent Generic) entered first in 12, the AG (Authorized (or licensed) Generics) entered first in 11. They both entered in the same month in three markets. Note that inabout half of the cases, the AG entered themarket after an IG (Independent Generic). However,in only two of the cases where it entered first, was the AG able to maintainthe highest share. Table 3 shows the status of the AG in January 2007and the timing of AG (Authorized (or licensed) Generics)entry.

Table 3. Status of the authorized generic after independent generic entry

	Number of molecules
AG entered beforethe IG (Independent Generic)	11
AG entered 1st and retained highest share	2
AG entered at thesame time as the IG (Independent Generic)	3
AG entered afterthe IG (Independent Generic)	12
Total	26
Data source: IMS (Intercontinental Medical Statistics) Health.	

The sample does not show a clear and consistent pattern of AG entering before IGs. Moreover, where they do enterfirst, AG (Authorized (or licensed) Generics),while they may obtain high market share for an initial period, retainleadership over time in only a small number of cases. [35]

Breadth of product line

As discussed further in section 4.A, given the commodity nature ofgeneric drugs, other things equal, pharmacies can reduce their costsby dealing with as few manufacturers as possible. This provides morediversified manufacturing firms with a competitive advantage overcompetitors with smaller product lines as they are able to bundle aportfolio of products across multiple therapeutic classes. [36] As indicated above, one means by which less diversifiedmanufacturers have been able to overcome this disadvantage has been byoffering lower net pharmacy prices.

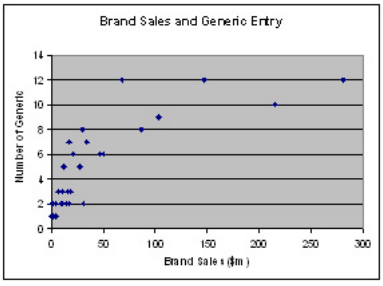
2.5 State of competition

The current competitive structure of the Canadian generic drugmanufacturing sector is significantly different from that of the early1990's. At that time, Apotex and Novopharm accounted for the majorityof sales in the domestic market (72.8%). [37] In 2006, although the twolargest firms remained Apotex and Novopharm, with approximately 50% ofsales, the top four firms accounted for under 72% of sales.

The dynamics of the generic drug manufacturing sector is alsobeing altered by increasing globalization. In 2000, Teva, a largeIsraeli generic drug manufacturer, entered the Canadian sector bypurchasing Novopharm. This was followed by the expansion into Canadaof Ratiopharm, a German generic drug company and one of the leadinginternational generic producers. The third Canadian largest supplier,Genpharm, was recently acquired by a U.S. (United States) generic company, MylanLaboratories from Merck, based in Germany. Indian genericmanufacturers have also entered the Canadian sector through the entryof Ranbaxy in 2005, and the acquisition of Taro by Sun Pharmaceuticalsin 2007.

An in depth analysis of the competition across the sector could not bedone as the information on such matters as the net pharmacy prices andmanufacturing costs for individual drugs was unavailable. [38] However, it appears that supply for many generic products ishighly competitive. The expiration of brand-name pharmaceuticalpatents can be met by the introduction of multiple genericproducts. The number of competitive suppliers is more likely to belarge in markets for popular molecules, the so-called blockbusterdrugs. Chart 1 shows the number of generic entrants per molecule andthe sales of the brand in the year prior to generic entry. As thechart indicates, molecules with large sales tend to attract a largenumber of generic competitors. [39]

Chart 1. Generic entry



Data source: IMS (Intercontinental Medical Statistics)Health.

The effects of the competition among manufacturers have traditionallynot been reflected in invoice prices for generic drugs. Rather, withprice competition focused on pharmacies, its effects are reflected innet pharmacy prices. As indicated above, these prices have beenestimated to be on average at least 40% below the invoice prices

usedby the PBPRB (Patented Medicines Price Review Board)and other pricing studies.

This suggests that other elements of the Canadian generic sectorcompetitive framework must be taken into consideration to explain thedifferences between invoice prices in Canada and other countries. Asnoted above, work done by the PBPRB indicatesthat although Canada ranks in the middle of six countries studied interms of the average number of generic suppliers for each non-patentedproduct, the country has substantially higher invoice prices forgeneric drugs than 10 of 11 countries covered in its 2006 genericprices study. [40]

3. Independent pharmacy distributors

Independent pharmacy distributors (IPDs) are thirdparty companies which acquire generic and brand drugs, as well asother products to distribute to retail pharmacies and hospitals. IPD play anincreasingly important role in the supply and management ofprescription pharmaceuticals. Well over 50% of all prescribedpharmaceuticals are distributed to pharmacies through IPD with this shareincreasing.

This section outlines the Canadian IPD sector anddiscusses its role in generic drug competition in Canada.

3.1 The Canadian IPD (Independent Pharmacy Distributors) sector

As independent intermediaries between the manufacturers and suppliersof drug store products, and pharmacies, IPD stock and supplya wide range of prescribed pharmaceutical products as well as typicalretail pharmacy products. These include over the counter (OTC) medicines, health and beautyaids, and confectionery items.

They may provide a variety of services including the following:

- Daily delivery or sometimes twice a day delivery, dependingon the location of the pharmacy
- Consolidation of purchases, reception and payments ofproducts by the pharmacy, including the management of expiredproducts and their return to the manufacturers
- Serving as a back-up source of supply for other wholesalers'customers or for a self-distributing chain, when the chain'swarehouse runs out of stock or closes for weekends
- Inventory management with continuous replenishment through alinked information system
- Electronic access to a product catalogue, product orders,billing and information research
- Controlled storage and temperature control of a variety ofpharmaceutical products
- Refrigeration systems for specialty products
- Inventory of high-value-low-turnover products.

Because of these services, distributors' costs include majorexpenses for warehousing, transportation, human resources andinformation systems. They may also help finance customers' inventoryby providing them with lines of credit.

McKesson Canada is the largest pharmacy distributor in the country. Itcarries more than 35,000 products, in 16 distribution centers. Itprovides logistics and distribution to over 800 manufacturersdelivering their products to 6,800 retail pharmacies, and 1,350hospitals, long-term care centres, clinics and institutions all overCanada. AmerisourceBergen Canada is the second largest distributor inthe country. It has 12 distribution centers and services independentretail pharmacies, national and regional chains, and hospitals. Kohl& Frisch Limited has 5 distribution centers across Canada. Otherdistributors, such as Unipharm Wholesale Drugs Ltd, UPE Group ofCompanies and McMahon Distributeur Pharmaceutique Inc., tend to be more regionallyfocused. [41]

3.2 Role of IPD (Independent Pharmacy Distributors)in the generic drug competitive framework

IPD (Independent Pharmacy Distributors) are one ofthree means by which generic drug manufacturers can distribute theirproducts. The others are through drugstore group self-distribution,and direct distribution by manufacturers.

Under self-distribution, distribution centres are maintained bypharmacy chain, banner and franchise groups, for supply to pharmacieswithin the group. Self-distribution involves similar roles andactivities to those of IPD (Independent Pharmacy Distributors),but within a group of pharmacies.

Major self-distributors include, Shoppers Drug Mart, Groupe Jean Coutu(PJC (Jean Coutu Group)), Familiprix Inc. (Incorporated), Lawton'sDrugstore, and London Drugs.

In direct distribution, as the name implies, manufacturers shipdirectly to drugstores.

IPD (Independent Pharmacy Distributors) arebecoming an increasingly important means for distributingpharmaceuticals in Canada. In 2006, they accounted for 57% ofpharmaceuticals distributed in Canada, other than to Wal-Mart. This is6% more than in 2002. Self-distribution also increased over thisperiod from 30 to 34%. In contrast, direct distribution fell by morethan half, to 9% from 19%.

Table 4. Share of pharmaceuticals ($) by distribution channel (DC)

	Distributor (%)	Chain DC (Distribution Channel)(%)	Direct (%)	Total (%)
2002	51	30	19	100
2003	54	30	16	100
2004	56	32	12	100
2005	57	33	10	100
2006	57	34	9	100
Source: Canadian Associationfor Pharmacy Distribution Management (CAPDM)Industry Trends Report, December 2006.				

According to those contacted for the study, the increased use of IPD is dueprincipally to their ability to provide their customers with one-stopshopping. While they play an important intermediary role in thesector, IPD (Independent Pharmacy Distributors)'impact on the competitive framework and pricing of generic drugsappears to be limited. According to interviews, IPD do not enterinto or maintain restrictive supply agreements or contracts with drugmanufacturers. They purchase pharmaceuticals from all manufacturers asrequired to meet their pharmacy customers' needs. Once a relationshipis established, purchases from manufacturers to distributors may beautomated to deliver inventory on time. The warehouse informationsystem can be connected to that of the manufacturer. When a product isneeded, it can be ordered electronically.

While ancillary terms may vary, such as discounts for promptpayment, the price paid by wholesalers for pharmaceuticals is based onthe provincial formulary or manufacturers' list price. In the case ofgeneric drugs, the price to distributors is discounted by thedistribution fee (or mark-up) allowing the drugs to be distributed topharmacies at their invoice price. According to sources, these feesare typically in the range of 5% of the value of the generic drugsdistributed. This is not the case with branded products, wheredistribution fees are typically paid by the pharmacy and are inaddition to the drug invoice price.

4. Retail and hospital pharmacies

Pharmacies and hospitals provide the main interface betweengeneric drug suppliers, patients and reimbursers. They are the mainfocal point for competition among generic manufacturers.

This chapter provides an overview of relevant features of theCanadian pharmacy and hospital sectors, and develops their role in thecompetitive framework for generic drugs.

4. A The Canadian retail pharmacy sector

4.A.1 Overview

There are more than 7,900 retail pharmacies in Canada. [42] In 2006, they purchased $15.74 billion worth of prescriptionpharmaceuticals and filled over 422,000,000 prescriptions. [43]The ten therapeutic classes of drugs most frequently dispensed byretail pharmacies in 2006 are indicated in the following table.

Table 5. Pharmacy sales by therapeutic class,2006

Rank 2006	Therapeutic Class	Purchases 2006 ($000,000s)
1	Cardiovasculars	2,409
2	Antihyperlipidemic agents	1,653
3	Psychotherapeutics	1,623
4	Antispasmodic/antisecretory	1,275
5	Analgesics	746
6	Bronchial therapy	718
7	Anti-arthritics	649
8	Hormones	634
9	Neurological disorders, miscellaneous	617
10	Diabetes therapy	567
Source: IMS (Intercontinental Medical Statistics) Health.		

Retail pharmacies in Canada are organized into a range ofbusiness structures. Key categories include the following:

Independents

An independent pharmacy is not affiliated with any corporatelyrun banner, franchise or chain program. The name of the store isunique to that store, and the owner controls, among other things,ordering, marketing strategies and store image.

Pharmacy groups

i. Banner
Banner pharmacies are independently ownedpharmacies that are affiliated with a central office. They pay feesfor the right to use a recognized name (such as I.D.A., Guardian,Uniprix, Price Watchers, Pharmasave) and to participate incentralized buying, marketing, professional programs and otherservices. While banner stores usually assume a required “lookand feel,” the stores themselves are independently owned andthe owners retain a high level of autonomy in areas such as localmarketing and professional services.

ii. Franchise
Franchise arrangements vary widely forretail pharmacies in Canada. The two largest franchises are ShoppersDrug Mart and Jean Coutu. The franchisees (or“associates” in the case of Shoppers Drug Mart) do notnecessarily own the physical store or the fixtures, and master leasesare usually held by the franchisor. However, they enjoy some autonomyin local marketing, buying and in-store services, as well as accessto programs developed by the head office.

iii. Chain
Chain pharmacies, such as Pharma Plus andLawtons, employ pharmacy managers who are salaried employees. Headoffice directs all marketing, merchandising, buying, and professionalprograms as well as other matters.

iv. Foodstore & Mass Merchandiser (“Food/Mass”)
Food and mass merchandiser pharmacies are departments withinsupermarket or mass merchandise outlets, such as Loblaws and WalMart. They employ salaried pharmacy managers (except in Quebec, whereregulations require pharmacists to own the dispensary). The managersfollow the direction of the head office for all marketing,merchandising, buying, professional activities, and other matters. [44]

As indicated in the table below, retail pharmacy groups, includingchain, banner and franchise pharmacies, collectively accounted forover 4,600 pharmacies in Canada in 2006, or about 58% of all retailpharmacies in the country. Food and mass merchandisers accounted for1,592 stores and independents for 1,686 stores, or about 20 and 21%,respectively. [45]

The allocation of Canadian retail pharmacies to the abovecategories has undergone substantial change over the past severalyears. Table 6 indicates that there has been a significant trend awayfrom independent pharmacies to other pharmacy categories. Over the2001 to 2006 period, while the total number of pharmacies increased bymore than 900 outlets, the number of independent pharmacies actuallyfell from 1,837 to 1,686.

While independents remain a major category, their share of allretail pharmacies fell from 31 to 21%. The total number of stores inboth other categories increased, with proportionately larger growth infood and mass merchandise outlets. These increased their share of allretail pharmacies from 14% to 20%. While the total number of chain,banner and franchise outlets increased, their share of all retailoutlets decreased slightly from 60% to 58%.

Table 6. Retail pharmacy count by category

Pharmacy Category [46]	2001	2002	2003	2004	2005	2006
Food/Mass Merchandisers	979	1,248	1,315	1,503	1,557	1,592
Independents	1,837	1,717	1,614	1,639	1,663	1,686
Source: CAPDM,Industry Trends Report, December 2006.						

Pharmacy Category [46]	2001	2002	2003	2004	2005	2006
Chain/Banner/Franchise	4,171	4,298	4,440	4,443	4,558	4,627
Total	6,987	7,263	7,369	7,585	7,778	7,905
Source: CAPDM,Industry Trends Report, December 2006.						

The two largest retail pharmacy groups in Canada are the Katz Group(Rexall), with over 1,100 outlets, and Shoppers Drug Mart (Pharmaprixin Quebec) with over 820 outlets. Collectively, they account for closeto 25% of all retail outlets in Canada. Other major retailers includeLoblaws, Pharmasave and Jean Coutu with, respectively, 470, 364 and320 outlets. Collectively, these five pharmacy groups account forabout 39% of all retail pharmacy outlets in Canada. [47]

The significance of individual pharmacy groups may vary significantlyfrom province to province. Although Jean Coutu has the fourth highestnumber of outlets in Canada, these are concentrated in Quebec wherethe company's share of retail outlets is in the range of 18%. The nextlargest group in the province, Familiprix, has over 260 stores,representing about 16% of all pharmacy outlets. [48]

Regardless of their category, retail pharmacies in Canadatypically have two main sources of revenue:

- Pharmacy operations, consisting of the dispensing of brandand generic prescription pharmaceuticals;
- Front store operations, consisting of the sale of OTC medication, health and beautyaids, general and seasonal merchandise. [49]

While the importance of these sources of revenue can varysignificantly according to pharmacy category, the following tableindicates that prescription drug sales are the principal source ofrevenue for all pharmacy categories. For all categories, prescriptionsales account for well over 50% of all revenues.

Table 7. Canadian front-store and dispensary revenue by pharmacy category

	Independent	Franchise	Banner	Chain	Food	Dept/Mass
Average Rx (Prescriptions) volume	45,600	81,000	57,500	39,100	38,300	55,400
Usual and customary fee($)	9.73	9.90	9.61	8.98	8.01	7.51
Rx (Prescriptions) share of sales (%)	79	59	74	71	71	72
Total Sales ($ million)	2.1	6.71	2.56	2.74	3.01	3.25
Source: 2006 Trends and Insights Online Report, The PharmacyGroup. [50]						

4.A.2 Role of retail pharmacies in the competitive framework for generic drugs

Retail pharmacies play a pivotal role in the competitive frameworkfor, and pricing of, generic drugs in Canada. Though they do notprescribe pharmaceuticals, after a drug has been prescribed,pharmacists normally have broad scope, under provincial andprofessional laws, policies and regulations, to substitute amonginterchangeable generic and brand drugs products when fillingprescriptions. [51] As well, to minimize theircosts, pharmacies have an interest in stocking only one, or a smallnumber of interchangeable products.

Because of this, competition among generic manufacturers andsuppliers to supply generic drugs to patients in the community hastended to focus on pharmacies. As indicated in the manufacturingchapter, this competition takes place in a variety of ways. Animportant dimension has been to grant rebates to retail pharmacies offpharmacy invoice prices.

Previous analysis of the Canadian pharmaceutical sector and testimonyprovided in recent hearings on amendments to Ontario's generic drugrelated legislation and regulations indicate that these rebatesprovide important returns to pharmacies. [52]

Rebates have also provided a financial incentive for retailpharmacies to substitute generic products for branded products. Asindicated in the manufacturing chapter and discussed further insection 5.A, off invoice rebates and discounts and other suchbenefits, have normally not been reflected in prices reimbursed bypublic and private insurers. Rather, those contacted for this studyindicated that reimbursed prices for newly introduced generic drugsreflect the former maximum limits under Ontario provincial drugbenefit legislation.

The following table shows the incentive provided to dispense genericdrugs through off invoice rebates and discounts, and their impact onthe profitability of pharmacies. The table is based on arepresentative branded drug prescription cost of $40 reimbursed underthe Ontario Drug Benefit (ODB (Ontario Drug Benefit))guidelines prior to the Transparent Drug System for Patients Act. Themaximum generic drug invoice price, based on the former Ontariomaximum generic drug price legislation is $25.20. [53] The table uses an allowablemark-up of 10% of the cost of pharmaceuticals. [54] Rebates are set at 40%. Inrecent Ontario provincial generic drug related hearings, this was thelower range of rebates paid on average to independent Ontariopharmacies. Dispensing fees are set at $6.54. [55]

Based on these numbers, the sale of a generic drug provides a netreturn to the pharmacy of $19.18 versus $10.54 for the brand product. [56]

Table 8. Historic pharmacy return on ODB (Ontario Drug Benefit) branded versus generic drugs sales

	Branded ($)	Generic ($)
Invoice Price	40.00	25.20
Allowable Markup(10%)	4.00	2.52
Dispensing Fee	6.54	6.54
Total (=Retail Price)	50.54	34.26
Rebates (40% of invoice)		10.08
Return (mark-up+dispensing fee+rebate)	10.54	19.14

In Ontario, pharmacy returns from the sale of generic drugs under ODB plans are being substantiallyaffected by the changes made to Ontario generic drug legislation andregulations in 2006. The maximum cost for generic products reimbursedunder ODB (Ontario Drug Benefit) plans has beenreduced to 50% of the interchangeable brand product, where more thanone generic is available.

Manufacturers are now prohibited from granting rebates on genericdrugs but they can provide professional service allowances in eightapproved categories. For drugs dispensed under ODB plans, these allowances mayequal up to 20% of product costs. For other drugs and other plans,there is no limit on the amount of professional allowances they canprovide. In addition to these changes, the maximum allowable mark-upfor ODB (Ontario Drug Benefit) drugs dispensed to ODB patients has been reduced to8% from 10% and maximum dispensing fees have been increased to $7.00from $6.54.

The implications of these changes on pharmacies' return on ODB sales are reflected in thefollowing table.

Table 9. Current pharmacy return on ODB branded and generic drugsales

	Branded ($)	Generic ($)
Invoice Price	40.00	20.00
Allowable Mark-Up (8%)	3.20	1.60
Dispensing Fee	7.00	7.00
Total(= Retail price)	50.20	28.60
Professional Allowances (20%)		4.00
Return(mark-up+dispensing fee+allowance)	10.20	12.60

Under the new Ontario legislation and policies, if maximumprofessional allowances are provided, pharmacies retain a financialincentive to dispense generic drugs for provincial plan beneficiaries.However the return to pharmacies in the form of rebates or allowancesis reduced by just over 75%, from $10.08 to $4.00. The total return,including mark-ups and dispensing fees, is reduced 34.2% to $12.60from $19.14.

Based on 40% rebates prior to the Transparent Drug System For PatientsAct, 2006, the net price received by the generic drug manufacturer on ODB (Ontario Drug Benefit) sales is higher underthe revised reimbursement framework. This framework, in effect,establishes a net pharmacy price floor at 40% of the brand drug price.By comparison, at 40% rebates under the previous ODB maximum price for multiplesource generics, the net pharmacy price received by manufacturers was37.9% of the brand price.

While the full impact of the new Ontario legislation and regulationson pharmacies and manufacturers is yet to be determined, as developedfurther in Chapter 5, the lower ODB (Ontario Drug Benefit)prices have not been extended to non-ODB drug sales for which there isno maximum allowance. In addition, private sales are not subject tomaximum dispensing fees or mark-ups.

It is anticipated that Quebec will receive the benefit of lowerOntario provincial drug plan prices because of their policy that theyreceive the lowest formulary prices offered in other provinces. [57] However, the potential impact of this change on pharmacies ismitigated by Quebec's pre-existing prohibition of rebates. Further,the province is also considering implementing a professionalallowances scheme parallel to Ontario's. [58]

4.B Hospital pharmacies

4.B.1 Overview

While retail pharmacies are the principal dispensers of drugs inCanada, hospital pharmacies also play a significant role. In 2006,they purchased $2.08 billion of drugs, compared to $15.74 billionpurchased by retail pharmacies.

Hospital pharmacists oversee the dispensing and storage of allmedicines given to patients in the hospital (in-patients). Generally,pharmacists in hospitals face greater clinical complexity inmedication management while community pharmacists face more complexbusiness and customer relations issues.

Under the Canada Health Act (CHA (Canada Health Act)),all necessary drug therapy administered in a Canadian hospital settingis insured and publicly funded. [59] Out-patient medications areoutside the Act's authority.

Provincial and territorial governments are responsible forproviding hospital care in their jurisdictions. This includesplanning, financing and evaluation of services, such as drugadministration and management. Drugs purchased for hospital patientsare covered by hospital budgets.

Hospitals maintain their own drug formularies listing all drugsavailable for prescription by a physician. Formularies tend to besimilar from one hospital to another within the same province.However, significant differences may be found from one province toanother, especially on expensive therapies such as cancer drugs.Hospital drug formularies tend to be more specialized than provincialor private plan formularies. This is due to the inclusion ofmedications that might be given only in a hospital setting, such asintravenous (IV (Intravenous)) drugs and othertherapies that must be provided on an in-patient basis.

Most hospitals have Pharmacy and Therapeutics (P&T) committees thatdetermine the drug selection for their formulary. Although thesecommittees are multi-disciplinarian, formulary decision-making tendsto be physician-driven. Physicians prescribe drugs for patients andthe hospital pharmacist ensures that they are available on theformulary. As in retail pharmacies, in cases where there are multiplesources for one drug (brand-name and generics), generic drugs willnormally be substituted for the brand drug unless the prescribingphysician has indicated “no substitution”.

In a retail pharmacy, drugs are dispensed for a specific number oftreatment days for acute symptoms, or for a 30-day to 90-day supplyfor chronic symptoms. The standard of care for a hospital pharmacy isto dispense drugs on a unit-dose — a single dose of the medication. Inunit-dose dispensing, medication is dispensed in a package that isready to administer to the patient. [60]

The main therapeutic classes of drugs used in hospital settingsdiffers greatly from retail pharmacies. Table 10 shows the top 10therapeutic classes of drugs dispensed in hospitals by purchase costin 2006. Cancer drugs are, by a wide margin, the largest class ofdrugs purchased by hospitals although they were not among the 10largest classes purchased by retail pharmacies. Cardiovascular drugs,the largest class of drugs purchased by retail pharmacies, were the9th largest class purchased by hospitals. In total, of the 10 largestclasses of drugs purchased by hospitals, only 3 ranked among the 10largest retail pharmacy categories.

Table 10. Top ten therapeutic classes byhospital purchases, Canada, 2006

Rank 2006	Therapeutic Class	Hospital purchases $(000,000s)
1	Oncology	557.3
2	Anti-Infectives, systemic	191.8
3	Hematinics	185.0

Source: IMS (Intercontinental Medical Statistics)Health.

Rank 2006	Therapeutic Class	Hospital purchases $(000,000s)
4	Hemostatic modifiers	164.4
5	Psychotherapeutics	120.3
6	Biologicals	101.2
7	Anti-virals	91.9
8	Immunologic Agents	72.5
9	Cardiovasculars	61.9
10	Hormones	56.1
	Top 10 hospital classes	1,602.5
Source: IMS (Intercontinental Medical Statistics)Health.		

4.B.2 Role of hospitals in the competitive framework for generic drugs

Differences in hospital versus retail pharmacy drug purchasesare also reflected in the ranking of generic manufacturers by hospitalsales. While diversified producers offer a wide range of products in avariety of forms, others may specialize in injectables or topicalapplication products that are more widely used in hospitals than inretail pharmacies. Table 11 indicates this. The table compares genericmanufacturers' rankings for sales to hospitals versus total sales tohospitals and pharmacies for molecules that lost patent protectionduring the 2001 to 2006 period.

Table 11. Ranking of hospital sales by genericmanufacturer, 2006

Rank Hospital Sales	Share of Hospital Sales (%)	Manufacturer	Rank Total Sales	Share of Total Sales (%)
1	32.67	Mayne Pharma	8	2.20
2	24.03	Sandoz	7	3.52
3	14.97	Novopharm	2	16.54
4	14.33	Apotex	1	38.61
5	6.92	Pharmascience	5	7.70
6	4.86	Genpharm	3	14.45
7	1.46	Ratiopharm	4	8.07
8	0.42	Taro Pharma	10	1.06
Data source: IMS (Intercontinental Medical Statistics)Health.				

Rank Hospital Sales	Share of Hospital Sales (%)	Manufacturer	Rank Total Sales	Share of Total Sales (%)
9	0.12	Cobalt	6	4.29
10	0.03	Hospira	17	0.00
	0.18	Others		3.56
	100	Total		100
Data source: IMS (Intercontinental Medical Statistics)Health.				

Mayne Pharma Canada was the largest seller of these genericdrugs to hospitals in 2006, but was the eighth largest genericmanufacturer measured by total sales including both hospitals andretail pharmacies. Sandoz, ranked seventh in total sales, was rankedsecond measured in hospital sales. Apotex, which had the highest totalsales, was ranked fourth in hospital sales only.

Prices for generic drugs used by hospitals are generally determined bynegotiations and contracting between the hospitals themselves and themanufacturers. While this may be done on a hospital by hospital basis,it is increasingly being done through group purchasing organizations (GPOs) or RegionalHealth Authorities (RHA (Regional Health Authority)s).

GPO (Group Purchasing Organizations)s, such asHealthPro, MedBuy and Contract Management Services, are stand aloneoperations whose shares are held by hospitals and other health careorganizations. They were established by hospitals and other healthcare facilities to economize on their goods and material costs byproviding centralized procurement and obtaining the benefits frombuying in higher volumes.

RHA (Regional Health Authority)s were establishedby most provincial governments in the 1980s and 1990s to amalgamatevarious health services, including hospital services, within regions. [61]Although RHA (Regional Health Authority)s mayparticipate in GPO (Group Purchasing Organizations)programs, they may also do their own group purchasing.

GPO (Group Purchasing Organizations) or RHA contracting processesare normally conducted in a public forum. The GPO or RHA will identify its needsfor products, usually by conducting a comprehensive review of theproducts consumed by each member and their respective annual volumesand unit costs.

A Request for Information (RFI (Request for Information))process may be used, gathering information from members and suppliers.Supplier information is sought later, allowing for an economicalvalue-added benefits analysis. These analyses are usually an integralcomponent of the Request for Proposal. [62]

A Request for Proposal (RFP (Request for Proposal)),outlining the market size, the items and conditions under which thecontract will be developed, is issued to all interested suppliers. Thecontract awarded is often a sole source agreement with the supplierfor participation by all of the GPO's members.

Contracts with brand/patented drugs manufacturers often include aright-of-first-refusal clause for cases where a generic drug becomesavailable during the term of the contract with the brand manufacturer.If the price of the generic drug is lower than the negotiated pricefor the brand/patented product, the GPO has the opportunityto sever the contract with the brand manufacturer.

In some cases, packaging, colour and/or shape of a drug can play acritical role in purchasing decisions. CPDs will often requesta sample of the drug to evaluate its appearance. To minimize medicalerrors in drug dispensing in hospitals, the appearance of a drug canmake a difference for the pharmacist. These factors may, at times,result in the purchase of a higher priced drug product.

As with retail pharmacies, drugs used by hospitals may be obtainedthrough IPD (Independent Pharmacy Distributors). Bystreamlining their pharmaceuticals procurement through an IPD, hospitals canbenefit from channel efficiencies, reduced inventory and decreasedadministrative costs.

- Competitive contracting processes may be used to obtain IPD services. Keyconsiderations are whether the IPD can:
- Service all members within its membership
- Provide simplified invoicing
- Guarantee delivery times
- Ensure IT (Information Technology) systemcompatibility for logistics management between the IPD and the GPO members.

Since drug prices are negotiated with the manufacturers, the mainpoint of negotiation with IPD is theirmark-up. Distribution and warehousing services are also negotiated.

According to persons contacted for the study, bidding for multiplesource generic products can be highly competitive. Rebates off invoiceprices are often included in the contract negotiations. In the case of GPO (Group Purchasing Organizations)s, manufacturerrebates are sent in a lump sum on a regular basis, usually quarterly,semi-annually or annually.

Table 12 indicates how hospitals pay relatively low invoice prices forgeneric drugs. The table compares invoice prices paid by hospitals toretail pharmacies for individual generic products, identified by DIN. The table does notreflect any off invoice rebates that may be paid to either retail orhospital pharmacies. For each province, for each drug, the ratiobetween the retail pharmacy and hospital unit invoice price wascalculated. [63]

Table 12. Inter-provincial pharmacy/hospitalprice ratio analysis, 2006

Generic Drugs	AB (Alberta)	BC (British Columbia)	MB (Manitoba)	NB (New Brunswick)	NS (Nova Scotia)	ON (Ontario)	PEI (Prince Edward Island)/ NL (Newfoundland & Labrador)	QC (Quebec)	SK (Sas
Mean	1.38	1.72	1.46	1.72	1.91	1.84	1.71	1.71	
Median	1.07	1.27	1.14	1.49	1.58	1.54	1.51	1.41	
Number of Drugs	507	537	474	263	217	680	299	752	

Data source: IMS (Intercontinental Medical Statistics)Health.

As indicated by the table, retail pharmacy invoice prices tendto be well in excess of hospital invoice prices. On average, pharmacyinvoice prices were approximately 39 per cent higher than hospitalinvoice prices, with differences within provinces ranging from 20% inSaskatchewan to 48% in Nova Scotia.

It was not possible to obtain data on any rebates provided tohospitals that are not accounted for in their invoices. To the extentsuch rebates are provided, they constitute a further gap between thenet price paid by hospitals and the retail pharmacy invoice pricesnormally reimbursed by private and public drug plans.

5. The generic drug reimbursement framework

Public and private drug plans cover about 98% of all Canadians. [64] Provincial plans cover about nine million Canadians with anotherone million covered by federal plans. These people include many inrelatively high use groups, such as seniors and persons suffering fromserious illnesses. A further 2/3 of Canada's population is covered byprivate prescription drug plans obtained through their employer orpurchased on an individual basis. [65]

Though covering fewer Canadians than private plans, public drug plans,reflecting the high use groups they cover, are the largest source offunding for retail prescription drug purchases in Canada. Of estimatedprescription Canadian drug expenditures of $21.1 billion in 2006,including pharmacy mark-ups and dispensing fees, public plansaccounted for an estimated $9.6 billion or 45.5%. Private insurersaccounted for $7.6 billion in expenditures or 36%. Out of pocketpayments for drugs, co-payments and other prescription drug expensesnot covered under either private or public plans accounted for $3.9billion in expenditures or 18.5%. [66]

The prevalence of public and private drug plans makes them keydeterminants of the competitive framework for generic drugs in Canada.This chapter examines relevant features of both categories of drugplans and their implications for the Canadian generic drug competitiveframework.

5.A. Public drug plans

5A.1. Scope and nature of public plans

In 2006, according to CIHIforecasts, the provinces and territories were the main providers ofpublic drug plans in Canada, accounting for about 84.2% of all relatedexpenditures. The remaining public plan expenditures are paid underfederal drug benefit plans and social security funds. The federal drugbenefit plan accounts for about 6.7% of the total expenditure andsocial security funds for about 8.8%. [67]

Public plan pharmaceutical product coverage

Public plans fully or partially reimburse drugs that are listed ontheir drug formularies. These are developed in consultation withexpert drug advisory committees and reflect individual plans' listingand reimbursement policies. [68] In order for genericproducts to be considered for formulary listing, the standard filingrequirements include the following:

- Consent to access information about the drug from variousagencies
- Confirmation from the manufacturer of its ability to supplythe drug
- Data indicating bio-equivalence to the brand drug product
- Health Canada NOC
- Price information
- Approved product monograph. [69]

In addition to meeting these filing requirements, generic drugs may also be subject to additional interchangeability requirements in order to be listed on a formulary.

Interchangeability can deal with factors beyond a drug'sbio-equivalence to a brand product. For example, bio-equivalent drugsmay not be deemed interchangeable with a reference brand product dueto:

- Difficult packaging or delivery devices
- A particularly bad taste
- The lack of a marking on a tablet allowing it to be easilydivided into two where such a marking exists on the brand referenceproduct.

If these or other characteristics of a generic product couldinterfere with the proper use or delivery of the drug, the product maynot be listed on the formulary.

The timing of the listing of generic drugs on public formularies canvary significantly across provinces, depending on the frequency withwhich provincial formularies are updated and reviews of generic druginterchangeability are conducted. [70]

Public plan beneficiaries

The coverage of public plans can vary substantially fromprovince to province. All provincial and territorial drug plansprovide coverage for seniors (New Brunswick and Newfoundland andLabrador apply an income test) as well as residents receiving socialassistance.

Through specific targeted programs, or more generally, throughplans available to all residents, all provinces and territories alsoprovide coverage for residents with specific medical conditions and/orwho may face exceptionally high drug costs. The specific medicalconditions most commonly covered are cystic fibrosis, diabetes,cancer, organ transplant, AIDS (Acquired Immune Deficiency Syndrome)/ HIV (Human Immunodeficiency Virus), and multiple sclerosis.

Four provinces offer universal eligibility for drug coverage: BritishColumbia, Alberta, Saskatchewan and Manitoba. The Ontario Trilliumdrug plan provides coverage to all residents who are not covered undera private plan and who have high drug costs relative to their income.Quebec maintains cost and income based drug plans that are availableto all residents who do not have private drug insurance. [71] New Brunswick, Nova Scotia, P.E.I. (Prince-Ewards-Island), Newfoundland and Labrador, andthe territories do not provide universal or general cost andincome-based programs.

There are six federal drug benefit programs, serving:

- First Nations and Inuit
- Veterans
- Members of the military
- RCMP (Royal Canadian Mounted Police)
- Prisoners in federal correctional facilities
- Refugees

The Non-Insured Health Benefits (NIHB) plan for FirstNations and Inuit is the largest of the plans accounting for 65% ofall federal plan expenditures in 2005-2006. The plans for Veterans andNational Defence are the next largest accounting for 22% and 7%,respectively. The remaining plans collectively account for about 6% offederal spending.

Reimbursement

Drugs covered by public plans are normally acquired by patientsfrom retail pharmacies. The amount reimbursed is determined by theapplicable public plan policy on allowable drug costs and pharmacymark-ups and professional fees, less any applicable patientco-payments and deductibles.

Limited exceptions to the delivery of pharmaceuticals through retailpharmacies apply in the cases of the Department of National Defense (DND) and NIHB. DND delivers drugsthrough 50 of its own base pharmacies located throughout Canada. Drugsupplies are also carried with DND when troops aredeployed in foreign theatres. While most NIHB costs are reimbursedthrough retail pharmacies, the plan also maintains nursing stations onremote reserves which receive supplies obtained through bulkpurchasing administered by The Department of Public Works.

5.A.2 Public plan generic drug related policies

Public plans may incorporate a variety of policies pertainingdirectly or indirectly to generic drugs. Key among these are thefollowing:

- Provincial interchangeability laws
- Formulary price caps
- Maximum cost reimbursement
- Net acquisition cost
- Standing offer contracting
- Most favoured nation provisions
- Deductibles and co-payments.

Interchangeability laws

Interchangeability laws provide the legal basis forinterchanging generic products and brand pharmaceuticals. The lawsgenerally apply to all interchangeable products, whether they aredispensed under public or private plans or paid for out-of-pocket.They generally consist of two elements:

- Provisions that allow pharmacists to interchangebio-equivalent products
- Provisions that protect the dispenser of the interchangeddrugs against related legal proceedings.

Interchangeability laws may be mandatory, requiring that thelowest cost interchangeable products be dispensed, or, they may bevoluntary, permitting, but not requiring, pharmacists to interchangeproducts.

Provinces having mandatory interchange laws include Saskatchewan,Manitoba, Newfoundland and Labrador, and Prince Edward Island.Newfoundland and Labrador and P.E.I. (Prince-Edwards-Island) further require that theinterchangeable product dispensed be the lowest priced productavailable. [73]

In the remaining provinces, Nova Scotia, New Brunswick, Quebec,Ontario, Alberta, and B.C. (British Columbia),legislation permits interchange, but does not make it mandatory.Pharmacists may substitute a prescribed drug with aninterchangeable drug. [74]

Most provinces' legislation also provides protection for pharmacistsfrom liability for any legal proceedings stemming from thesubstitution of an interchangeable drug, provided that substitution islegally allowed in that province. [75] However, in all provinces,physicians can prevent interchange of generic products by indicatingthat "no substitution" is to be made. This may occur where there is amedical reason why a patient must receive a specific brand of drug.Also, a patient may request "no substitution" and pay any additionaldrug costs out-of-pocket.

Formulary price caps

Under formulary price caps, a generic drug must be priced at orbelow a maximum price in order to be listed on a public planformulary. Two provinces, Ontario and Quebec, currently use price capsto limit maximum prices for generic drugs under their provincialformularies.

In Ontario, under the Transparent Drug System for PatientsAct, 2006, generic drugs normally must be priced at no more than 50%of the reference brand product price in order to be listed on the ODB formulary. There are limitedexceptions to this rule. Where there is evidence that the genericproduct would be the only drug product of its type designated asinterchangeable with an original drug product, the drug price may benegotiated between the provincial drug plan and the drug manufacturer.This price may be higher than the 50% maximum, but lower than theprice of the original product. [76]

In Quebec, a regime is being implemented under which the price of thefirst generic drug will be limited to 60% of the price of thereference brand product. The price of subsequent generic drugs will belimited to 54% of the brand-name drug. [77]

In Ontario, after an initial formulary price is established,subsequent price increases are regulated.Changes to the drug benefitprice of products on the provincial drug plan formulary are subject toapproval by the Executive Officer of Ontario Public Drug Programs.

Quebec implemented a policy in 1994 preventing price increases fordrugs listed on the province's formulary, except in certaincircumstances. [78] However, the province is inthe process of implementing a mechanism to allow drug price increasestied to the province's consumer price index. [79]

Maximum generic cost reimbursement

Maximum generic cost reimbursement policies, generally listed underprovincial plans as maximum allowable cost or lowest cost alternativereimbursement policies, do not prevent generic drugs from being listedon public plan registers if they are relatively high priced. [80]Instead, they provide an incentive to dispense low cost genericsby stipulating a maximum amount that will be reimbursed for a group ofinterchangeable products. If a higher cost brand or generic product isdispensed, the difference must be paid by either the patient or the pharmacy.

Maximum cost reimbursement policies apply in all provinces as well asthe Yukon. [81] In most cases, maximum cost reimbursement prices are obtained frommanufacturers. The exception is B.C. (British-Columbia), which sets maximum reimbursement cost based on pharmacy pricesobtained through its Pharmanet system.

As with interchangeability policies, exceptions may be made tothe maximum generic cost reimbursement policies in limitedcircumstances. For instance, if a patient must receive a particulardrug for medical reasons, or the lowest cost product is unavailabledue to a supply shortage, provincial drug plans may reimburse the costof a more expensive product, with no additional cost to the patient.

Net acquisition cost

Pharmacies actual acquisition costs of drugs, whether they arepatented or no longer patent protected, are used by many provinces asa basis for reimbursing drugs under their public plans, subject to anyapplicable maximum price or cost reimbursement policies. In theseprovinces, the maximum amount that can be reimbursed for generic drugsis the lower of the pharmacy actual acquisition cost or the maximumgeneric cost reimbursement price.

In some provinces, regulations or policies further stipulate that theactual acquisition costs reported by pharmacies should be the netacquisition cost, incorporating the value of any purchase pricereduction, rebate, allowance, free products, or discount received bythe pharmacy or dispensing physician. These provinces are Nova Scotia,New Brunswick, Quebec, Saskatchewan and British Columbia. [82]

Standing offer contracting

Standing offer contracting involves the use of a competitive biddingprocess to establish the maximum price that will be reimbursed. Thewinning manufacturer guarantees delivery of the specific drug at thecontracted price. In return, the manufacturer's product is givenpreference or used exclusively during the contract period. [83]

A number of provinces have attempted or considered using astanding offer contract process. However, Saskatchewan is the onlyprovince currently following this approach. The province uses standingoffer contracting for 91 high volume interchangeable drug groups.

Most favoured nation provisions

Most favoured nation provisions require that the price offeredto a provincial drug plan by a manufacturer for a particular drugproduct be no more than the lowest amount charged to other provincialdrug plans elsewhere in Canada.

Most favoured nation provisions currently apply under the drug plansof two provinces: Quebec and Newfoundland and Labrador. [84] In Quebec, all generic drug manufacturers must sign a commitmentthat they will submit a guaranteed selling price for any drug theywish to have entered on the list of medications. [85] The guaranteed selling pricemay not be higher than any selling price granted by the manufacturerfor the same drug under other provincial drug insurance programs. [86]

In Newfoundland and Labrador, in order to have a product listed on theformulary, the manufacturer must provide for a specific period, aguaranteed price for the product that is no higher than the best priceavailable elsewhere in Canada. [87]

Deductibles and co-payments

Deductibles are amounts that patients covered by drug plans mustspend on prescription drugs before the plan will begin to reimbursecosts. Co-payments are amounts that beneficiaries are required to payfor prescription drugs that are partially reimbursed under a drugplan.

Provincial drug plans typically implement deductibles andco-payments as a means to keep overall drug plan costs down and todiscourage over-use of prescription drugs. However, withinterchangeable generic drugs, significant deductibles and co-paymentsmay also provide incentive for patients to search for lower pricedproducts.

Co-payments and deductibles are required under many public drug plans.While in many cases they are limited, in some, plan beneficiaries canspend substantial amounts. For example, under the B.C. Universal Fair Pharmacare plan,those under 65 years of age are required to make co-payments of 30%amounting to 2 to 4% of their total family income beforepharmaceuticals will be fully reimbursed. Under the SaskatchewanSpecial Support Program, a deductible of up to 3.4% of annual familyincome applies. Under Manitoba's Pharmacare program, deductibles

arebetween 2.32% and 5% of adjusted family income. The Ontario Trilliumdrug program similarly has an income based deductible. The Albertaprovincial drug plan requires residents to make co-payments of 30% toa maximum amount of $25 per prescription.

5.A.3 Public plan generic drug policies competitive effects

Despite differences among their generic drug plan policies, reimbursedgeneric prices tend to vary little between the provinces. Thefollowing table indicates this, comparing invoice prices of genericdrugs in retail pharmacies. The table compares 2006 average invoiceprices for 579 generic drugs sold by prescription in retail pharmaciesin nine provinces for which data were available. [88] For each drug, the unitinvoice price in each province relative to the national average unitinvoice price was calculated.

Table 13. Average unit pharmacy invoice prices of generics relative to Canada average, 2006

	AB (Alberta)	BC	MB (Manitoba)	NB (New Brunswick)	NL	NS (Nova Scotia)	ON (Ontario)	QC (Quebec)	SK (Saskatchewan)
Mean	0.979	1.021	0.979	1.021	0.992	1.016	1.010	0.972	1.009
Median	0.998	1.031	0.992	0.998	1.000	0.997	1.000	0.985	0.998

Data source: IMS (Intercontinental Medical Statistics)Health.

In all provinces, average generic prices are within 2.5% of thenational average. Median prices are within 1.5% of the nationalaverage. [89]

Those interviewed for this study generally indicated that there islimited competition in generic drug provincial formulary pricing.Prices in all provinces for initial and successive generic drugproducts are generally considered to reflect the former maximum priceguidelines under Ontario legislation and regulations. Under theguidelines, the first generic listed on the ODB formulary was to be priced atno more than 70% of the brand equivalent. Subsequent generics were tobe priced at no more that 90% of the price of the first generic.

This view exists despite public plans policies designed toensure that low cost generics are dispensed. These policies aregenerally considered to have played an important role in ensuring thatthe lowest priced generic drugs on provincial formularies aredispensed or reimbursed. They also help guarantee a minimum level ofcost savings from generic drugs. However, they have not generatedstrong competition among generic drug manufacturers to reduce theirpublic plan list and formulary prices.

This observation is consistent with incentive structure undermost public plan designs. Interchangeability policies, while theyprovide a basis for substituting lower for higher cost drugs, do not,in themselves, provide incentives for companies to reduce theformulary prices reimbursed by public plans.

Maximum cost reimbursement policies similarly provide limitedincentives for generic drug manufacturers to compete on price byoffering lower formulary prices. Key competitive features of thesepolicies include:

- The price of the lowest cost product is publicly listed onprovincial formularies, or maximum allowable cost or least costalternative prices lists.
- Competing generic drug manufacturers can protect theircompetitive positions by matching formulary price decreases offeredby other manufacturers.

- Generic drug manufacturers that are the first to offer lowerformulary prices are generally not given preference under publicplans.

Due to these features, a manufacturer offering a lower formularyprice to a public plan may have a limited opportunity to gainsignificant market share while decreasing its return on sales.Instead, other manufacturers can protect their competitive positionsby offering matching formulary price decreases.

Net acquisition cost policies that are aimed at capturing thevalue of rebates and other such benefits potentially allow publicplans to increase their benefits from competition among genericmanufacturers. However, the monitoring and auditing capabilities ofpublic plans has traditionally focused on pharmacy invoices that donot capture off invoice rebates, discounts and other benefits.

Establishing a framework to ensure that such benefits arecaptured would require much more extensive auditing capabilities toallow public officials to broadly examine pharmacies' operations andfinances. In designing an effective net acquisition cost policy, anadditional concern would be to avoid interfering with efficiencyenhancing or normal business terms, such as volume or loyaltydiscounts and prompt payment rebates.

Public plan maximum formulary price policies require genericdrugs to be priced at or below a maximum price relative to theirinterchangeable branded products. This potentially gives provinces themeans to ensure a minimum cost saving for generic drugs. However,these policies do not reflect either the development and supply costsnor the competitive prices of generic drugs. Further price regulationof this nature runs the risk of preventing the supply of high costgeneric drugs for which the development cost is higher than theallowable price.

Most favoured nation policies, while intended to ensure that aprovince's generic drug prices will be no higher than those of otherpublic plans, can act as a disincentive for manufacturers to competeby offering lower formulary prices to other public plans. They may dothis by ensuring that low formulary prices initially offered in oneprovince will be automatically extended to other provinces having mostfavoured nation policies. Even if the initial offering of the lowprice conveys a competitive advantage in the first province, this willresult in a lower price being received by other provinces with mostfavoured nation provisions.

As noted, significant deductibles and co-payment requirements applyunder various public plans in Canada. However, no indication wasprovided by research or interviews that these have led to generic drugprice competition among pharmacies. In any case, if co-payments anddeductibles are increased as an indirect means to promote generic drugcompetition, the issues of health care quality and access would haveto be addressed. [90]

Where it has been possible to apply, standing offer contractingappears to provide significant competitive benefits. As noted,Saskatchewan is the only province obtaining pharmaceuticals throughthis approach.

Of the 91 drugs for which standing offer contracting is used,information on 37 drugs, which were also sold in other provinces (andwere part of provincial reimbursement claims), was available. [91] The following table compares current Saskatchewan generic drugformulary prices for this set of drugs to prices in British Columbia,Saskatchewan, Manitoba, Quebec and Ontario, expressed as a percentageof the brand product price. [92] On average, Saskatchewan paysthe lowest percentage of the brand price, about 42%. Ontario has thenext lowest average price, 46%, reflecting the recent maximumformulary price caps implemented in the province.

Table 14. Current formulary listing price ofgenerics drugs as a percentage of the brand price

	BC (British Columbia)	SK (Saskatchewan)	MB (Manitoba)	QC (Quebec)	ON (Ontario)
Data source: Brogan Inc. (Incorportated)					

	BC (British Columbia)	SK (Saskatchewan)	MB (Manitoba)	QC (Quebec)	ON (Ontario)
Mean	0.59	0.42	0.58	0.65	0.46
Median	0.61	0.43	0.61	0.63	0.47
Number of Drugs	37	37	37	36	34
Data source: Brogan Inc. (Incorportated)					

While increased direct contracting by public plans may have thepotential to increase their benefits from competition amongmanufacturers, parties with whom this matter was discussed pointed toa number of related obstacles and issues to be addressed. Theyinclude:

- Ensuring that such contracting promotes or sustainscompetition among generic manufacturers, rather than results in aconcentrated and uncompetitive generic drug supply sector.
- The need to effectively and efficiently integrate contractingpractices and pharmacy operations.

In addressing the first of these issues, it would be importantto ensure that competitive contracting is designed to protectcompetition through successive rounds of contracting. Processes thatresult in the exit of manufacturers over time may ultimately lead to aloss of effective competition.

On the second issue, in effectively integrating contractingpractices and pharmacy operations, it is important to consider how todeal with existing inventory when there is a change in contractedmanufacturers. A further consideration may be ensuring that differentinterchangeable products remain available to deal with circumstanceswhere a contracted generic product cannot be used by a patient formedical reasons.

Reliance on competitive contracting also places greater emphasison successful bidders being able to supply the market, and mechanismsto ensure that alternative sources are available where a contractor isunable to meet demand.

The practices noted above are not the only ones that might beconsidered to shift the focus of generic competition to public plans.Others might involve, for example, restricting access to formulariesas a means to encourage price reductions.

Practices shifting the focus of generic competition to publicplans, away from pharmacies, in any case, would increase emphasis onthe regulation of pharmacy professional fees and mark-ups. As thesepractices would limit the potential to provide rebates or professionalallowances by generic drug manufacturers, they would tend to makepharmacies more reliant on professional fees and mark-ups, and wouldmake the pharmacy net returns more transparent.

5.B Private drug plans

5.B.1 Overview

Private drug plans generally complement public plans by coveringpersons or costs not covered by the public plans. As noted, abouttwo-thirds of Canadian residents are covered by private insurance.According to the CIHI,private insurers, including group and individual insurance, paid $7.6billion for prescription drugs in Canada in 2006 representing 35.8% oftotal prescribed drug expenditures. [93]

This section describes the private drug plans sector in Canadaand its role within the competitive framework for the generic drugs inCanada.

5.B.2 The Canadian private drug plans sector

While individuals may purchase private drug insurance, group benefitplans provide approximately 95% of private coverage in Canada. [94] These plans are normally sponsored by or organized by employers,or professional orders or associations. In choosing the level and typeof coverage to provide, plan sponsors look for a balance between morecomprehensive coverage (desired by plan members), managing their riskexposure, and minimizing their drug coverage or insurance premiumcosts.

Plan sponsors have the option of providing either fixed cost(insured), or uninsured plans for their members.

Insured plans

Under insured plans, drug costs are principally reimbursed bythe drug plan provider. These groups pay a "premium" per employee orfamily. Smaller groups usually choose the premium method of funding asa means to manage their risk. Premiums include the cost of anticipatedclaims expense, administration costs, a charge for risk and anestimate for claim cost increase. At renewal time the claimsexperience is analyzed. If the rate varies from what was anticipated,this may be reflected in either higher or lower rates on renewal.

Administrative services only

Larger groups are more likely to sponsor uninsured oradministrative services only (ASO) plans as the size of theirmembership can adequately diversify their exposure to risk. Thesegroups choose to self insure which means they pay the claim costs plusa percentage or per claim fixed charge for administration. Since thegroup assumes the risk of large claims, no risk charge needs to beincorporated.

Insured and ASO drug plans are provided in Canada by bothfor-profit insurers, such as Great-West Life, Manulife and Sun-Life,and not-for-profit companies, such as Green Shield Canada, AlbertaBlue Cross and Medavie Blue Cross.

The administration of these plans is complex and highlytechnical. It requires:

- Maintaining and updating drug formularies
- Developing and maintaining a network of pharmacies
- Claims adjudication
- The manual and electronic processing and settlement of drugclaims
- Expertise in the analysis and assessment of claimsinformation
- Expertise in the development of coverage and reimbursementpolicies
- Expertise in the development of flexible software solutions
- Coordination with provincial plans.

Non-profit drug plan providers, such as Blue Cross and Green ShieldCanada, have developed capabilities to provide these services fortheir own and other group plans that they administer. [95] For-profit drug planproviders widely contract out the electronic processing and settlementof claims to third party pharmacy benefits managers (PBMs).

PBM (Pharmacy Benefit Manager)s serve asintermediaries between the plan provider and the pharmacy to settleclaims. They may also provide other pharmacy benefit managementservices listed above. In some cases, PBMs may deal directly withemployer or other plan sponsors rather than through a plan provider.ESI Canada and Emergis are the two largest PBMs in Canada. OtherCanadian PBM (Pharmacy Benefit Manager)s includeClaimSecure and Nexgen Rx (Prescriptions).

5.B.3 The role of private drug plans in the generic drug competitive framework

Private plans may adopt similar policies to those used by public planson generic drug pricing and interchangeability. It has been statedthat in Canada, provincial government drug plans have structured thepricing and gross margins that both public and private plans pay. [96]

The view is supported by the following table comparing genericdrug costs reimbursed by provincial plans in comparison to privateplans. Drugs covered in the table include both generics and brand-namedrugs that have lost patent protection. They were both public andprivate plans reimbursement claims in 2006.

Prices used for constructing the table include both drug costsand pharmacy mark-ups reimbursed. For each drug, the average unitprice in Canada was calculated. The ratio between the national averageunit price paid by a public plan and the unit price paid by a thirdparty payer was computed. The table shows descriptive statistics ofthe ratios between the unit prices paid by the provinces on averageand the private plans.

For both brand-name and generic drugs, the prices paid byprivate plans tend to be higher than the price paid by the publicplans. On average in 2006, non-patented brand, per unit, cost publicplans about 90% of the cost of private plans. For generic drugs only,the ratio was 93%.

Table 15. Public plans versus private plans unit price ratio, 2006

	Non-patented Brand-name Drugs	Generic Drugs
Mean	0.90	0.93
Median	0.93	0.93
Standard Deviation	0.11	0.05
Minimum	0.40	0.62
Maximum	1.22	1.19
Number of Drugs	378	245
Data source: Brogan Inc. (Incorportated)		

The higher prices paid, on average, by private plans versus publicplans may reflect the granting of higher mark-ups by private plans ortheir payment of higher drug prices than the provinces. [97]

This relationship between public and private plan generic drug pricesis undergoing change. Although Ontario legislation has capped genericdrug prices under ODB (Ontario Drug Benefit) plansat 50% of the brand price where more than one generic is available,these prices are not being provided to private plans in Ontario.Consequently, a two-tiered price structure exists in the province forgeneric drugs. Further concern has been expressed that not

onlyprivate plans do not currently benefit from lower generic prices inOntario, private plan prices may increase to compensate for the lostrevenues on ODB (Ontario Drug Benefit) sales underthe reduced ODB (Ontario Drug Benefit) maximumgeneric drug prices.

The limited role of insurers and PBMs in seeking lower costgeneric drugs is an important difference between the generic drugcompetitive frameworks in the US (United States)and Canada. In the US (United States), insurerowned and independent PBM (Pharmacy Benefit Manager)sare highly active in negotiating generic drug rebates or discountsfrom manufacturers. These can provide important savings on drugs costsfor plan sponsors. [98] Determining the reasons forthis difference between the Canadian and Us generic drug sectors wasbeyond the scope of this study.

6. Summary of key findings

Generic drugs play an important role in helping to manageCanada's health care costs. Generics are developed and manufactured tobe substitutable for branded drugs. Their role is to providecompetition for patented drugs when their patent protection ends dueeither to the end of their period of patent protection or when thepatents are found to be invalid.

Competition between generic and brand pharmaceuticals takesplace within a unique competitive framework. Key elements of thisframework are as follows.

Demand

Demand for prescription drugs is determined by a prescribingphysician. Physicians' main concern selecting a drug is its perceivedeffectiveness in treating a condition. The physician does not have adirect financial interest in the drug that is eventually supplied.

Patients normally obtain their prescribed drugs from retailpharmacies located in the community. Many patients are insensitive tothe price they pay for generic drugs as they bear none or only a smallportion of their drug costs under their public and private drug plans.An estimated 98% of Canadians are covered by these plans.

Dispensing

The choice of which generic product to dispense, except in caseswhere a prescribing physician indicates that no substitution ispermitted, is generally made by the pharmacist from products in stockin the pharmacy. This choice is subject to provincial laws,regulations or policies allowing brand products and their genericproducts to be dispensed interchangeably. In some cases, patients mayplay a role where they wish to obtain the brand product or aparticular generic product.

Pharmacies' decision of which generics to stock and dispensereflects a number of considerations. Pharmacies stock one or a smallnumber of generic products to keep inventory management costs down.The decision regarding which generic(s) to stock takes into accountthe invoice price of the product net of any rebates or allowances.Other terms and conditions, such as reliability of supply, or possiblebenefits of dealing with suppliers providing a broad range rather thana small number of products are also taken into account.

The net pharmacy price has traditionally been a majordeterminant of product selection in most jurisdictions in Canada.However, recent legislation in Ontario restricting the granting of offinvoice rebates and allowances is likely to increase the importance ofother considerations, such as the breadth of product portfolio,particularly for sales

under Ontario Drug Benefit plans. Rebates havebeen prohibited for a number of years in Quebec and have recently beenthe subject of a number of court cases.

Reimbursement of the price paid by consumers for generics dispensed byretail pharmacies is based on public and private drug plans' formularyand reimbursement practices. Private plans' practices tend to mirroror complement public plans' practices. These practices typically basethe amount that is reimbursed on the lowest priced generic product onthe formulary. These prices generally reflect invoice or list pricesand do not include off invoice rebates. Ontario has maximum formularyprice restrictions for its public drug plans. In October 2006, theprovince reduced maximum reimbursement prices for generic prices to anorm of 50% of brand prices. The previous formula stated that mostproducts could be priced at no more than 63% of the brand price. [99]

Hospital pharmacies account for a significant share of genericdrugs demand, particularly for drugs normally provided on anin-patient basis. They obtain much of their needed pharmaceuticalsthrough competitive tendering processes. Hospitals pay for theseproducts out of their budgets and they are dispensed to patients freeof charge under the public health care system.

Distribution

Generic drugs are distributed to pharmacies and hospitals eitherthrough independent pharmacy wholesalers and distributors (IPD), selfdistribution to pharmacy groups such as chains, banners store andfranchises, or manufacturer direct shipments. IPD are becoming anincreasingly important means for distributing products. They offerservices to all manufacturers providing them with an alternativemeans, besides direct distribution, for getting their products topharmacies that do not self distribute.

Manufacturing

Manufacturing of independent generic drugs involves significantdevelopment and regulatory approval costs. Researchers work to developa drug that is bio-equivalent to the brand-name reference product.Regulatory approval to sell an independent generic drug in Canadainvolves obtaining a NOC (Notice of Compliance) fromHealth Canada addressing related patent claims and the bio-equivalencyof the generic drug with the brand product. According to thosecontacted for this study, from the time a decision is made tointroduce a generic product, manufacturers may require between threeto six years to bring the product to market. Sunk costs may be in therange of $3.5 million (including costs for bio-equivalence studies,development and regulatory approval) for a small molecule. Costs canvary widely depending on the complexity of the product, the potentialto spread development costs across international markets, the scopeand nature of any associated patent litigation and the cost forbio-equivalence or clinical studies. Obtaining approval to supplyauthorized generics (AG (Authorized (or licensed) Generics))involves much lower costs as these products are the same as the brandproduct already being supplied.

Key determinants in whether to supply a generic product include:

- Demand size and competitors: The projected aggregate demandsize of the reference brand product as well as the relatedtherapeutic class play an important role. First, the genericmanufacturers take into consideration how many manufacturers areexpected to introduce competing generic versions of the targetedmolecule. Second, branded companies may in some cases provide addedcompetition to the generic manufacturer by introducing: (i) acompeting drug within the same therapeutic class, or (ii) brandextensions to replace older formulations whose patents are about toexpire. Brand extensions may reduce the potential demand

sizeavailable to the generic industry once the original drug loosespatent protection with a proportion of patients being prescribed thenew version.

- Development and approval costs: An important part of theentry decision is the evaluation of the total costs of introducing ageneric drug to the market. These costs include drug development,bio-equivalence and/or clinical studies and federal and provincialapprovals.
- Timing: The length of time it would take to develop theproduct and obtain approval from Health Canada is a crucialconsideration. This is particularly so if it results in the laterelease of a generic product following the loss of patent protectionby the relevant brand product.
- Specialization and product portfolio: The manufacturer mayhave been involved in some related work, or it may specialize inproducing drugs within a certain therapeutic class or specialize incertain dosage forms(creams, ointments, injectables), therebybenefiting from economies of scale or scope in production. On theother hand, manufacturers may wish to supply a molecule to make theirproduct portfolio more attractive to customers.
- Legal challenge costs: Challenging brand patents, can be acostly and time-consuming process. A generic manufacturer alreadyinvolved in legal challenges may decide not to enter into anotherchallenge.

While it has not been possible to conduct a full assessment ofgeneric competition, within this framework it appears that strongcompetition takes place among manufacturers in the supply of manygeneric drugs in Canada, particularly those products having highannual sales. Whereas in the past the industry was dominated by twolarge Canada based suppliers, there are now 15 generic drug suppliersin Canada. Many have ownership and other relations with major globalgeneric drug manufacturers. The ending of patent protection for a drugcan result in the entry of multiple suppliers.

Granting of off invoice rebates to pharmacies has traditionally beenthe principal means by which manufacturers have competed with eachother. [100] It has not been possible to obtain detailed evidence regardingthe size of these rebates. However, public sources and informationprovided by parties interviewed for the study indicate that netpharmacy prices have been, on average, at least 40% below the invoiceprice, and as much as 80% lower in some cases. These rebates haveprovided incentives for pharmacies to substitute generic drugs forbrand products and have been an important source of income for them.It may be noted that competition in the form of rebates, by itsnature, is not reflected in price studies comparing invoice prices inCanada versus other countries.

Off invoice rebates provided to pharmacies have typically not resultedin lower prices to consumers nor to public and private drug plans.While the plans may incorporate specific generic drug relatedpolicies, they provide limited incentive for pharmacies ormanufacturers to compete to supply the plans through lower formularyand reimbursement prices. Rather, these prices, in all provinces, havetended to reflect maximum allowable prices under the Ontario's former ODB (Ontario Drug Benefit) maximum priceregulations. Other than the ODB (Ontario Drug Benefit)sales that are covered by Ontario's new maximum price regulations,this pricing is continuing. Consequently, in Ontario a two-tieredpricing framework exists for ODB (Ontario Drug Benefit)plan sales versus sales of drugs for private plans or persons payingout-of-pocket. [101]

Alternative public and private drug plan approaches that focuscompetition on reimbursers, could result in important cost savings forinsurers. However, further consideration of these approaches isrequired in order to assess the barriers to their implementation, howthey may be integrated into the current pharmacy and drug planframework, and how they may be designed to promote and sustaineffective competition among manufacturers.

Appendix 1: Federal regulatory framework for pharmaceutical products

Overview

All drugs that are marketed in Canada are subject to the Foodand Drugs Act [102] and Food and DrugRegulations. [103] The Food and DrugsAct defines a drug as in part as "any substance or mixture ofsubstances manufactured, sold or represented for use in the diagnosis,treatment, mitigation or prevention of a disease, disorder, abnormalphysical state, or its symptoms..., restoring, correcting, ormodifying organic functions..., or disinfection in premises in whichfood is manufactured, prepared or kept". [104]

Whether a product is categorized as a "drug" depends on its composition (medicinal value leading to a pharmacological effect), and/or what claims are made for the product.

Part C of the Food and Drug Regulations requires a manufacturer to obtain a Drug Identification Number (DIN (Drug Identification Number)) prior to selling adrug in Canada. [105] A manufacturer or distributor is defined as "a person, including an association or partnership, who under their own name, or under a trade-design or word mark, trade name or other name, word or mark controlled by them, sellsa food or drug".

In regulatory terms, the "manufacturer" of a drug isnot necessarily the company that makes the product, but the company towhich the product is registered at the time of approval. Themanufacturer may be located outside Canada, but there must be someonein Canada who is responsible for the sale of the drug.

Health Canada is responsible for ensuring compliance with theregulations and non-compliant products are subject to action.

Pre-market drug submission requirements

New drugs can be sold in Canada once they have successfully passed areview process to assess their safety, efficacy and quality. HealthCanada's Health Products and Food Branch (HPFB)is responsible for this review process. [106]

A drug may be regulated as a new drug when it has not been on themarket in Canada for long enough or in sufficient quantity to haveproven its safety and effectiveness under conditions of use. As wellas a DIN (Drug Identification Number), a new drugmust have a Notice of Compliance (NOC) with PartC of the Food and Drug Regulations issued before it can besold in Canada.

A New Drug Submission (NDS (New Drug Submission))typically involves between 100 and 800 binders of data, containingscientific information about the product's safety, efficacy andquality. It includes:

- The results of both the pre-clinical and clinical studies
- Details on the production of the drug and its packaging andlabeling
- Information about its claimed therapeutic value
- Information about its conditions for use and side effects.

A clinical trial does not have to be performed in Canada for a New Drug Submission or a DIN Application.

When a generic drug enters the market, Part C of the Food andDrug Regulations allows the manufacturer to file an Abbreviated NewDrug Submission (NDS). The NDS contains data that demonstratethe drug's bio-equivalence with a Canadian reference product. ACanadian reference product is defined as a drug which has been issuedan NOC

and whichis marketed in Canada by the innovator of the drug. Where theinnovative drug (brand-name drug) is no longer marketed in Canada, adrug acceptable to the Ministry of Health can be used to demonstratebio-equivalence.

The NDS must meet the same qualitystandards as an NDS (New Drug Submission) and thegeneric product must be shown to be as safe and effective as thebrand-name product. An NDS typically involves between 10and 20 binders of data. It includes scientific information on thegeneric product's performance compared with the brand-name product,and provides details on the production of the generic drug, itspackaging and labeling.

Generics do not have to replicate the extensive clinical trialsthat have already been done when the original, brand-name drug wasdeveloped. Those trials usually involve a few hundred to a fewthousand patients. Since the safety and efficacy of the brand-nameproduct has already been well established in clinical testing andoften many years of patient use, it is not scientifically necessary,and would be unethical, to require that such extensive testing berepeated for each generic drug that a firm wishes to market. Instead,generic applicants must scientifically demonstrate that their productis bio-equivalent (i.e. (for example), performs in the same manner) as the pioneerdrug, within an acceptable range.

One way scientists demonstrate bio-equivalence is to measure thetime it takes the generic drug to reach the bloodstream and itsconcentration in the bloodstreams of 24 to 36 healthy, normalvolunteers. This gives them the rate and extent of absorption orbio-availability of the generic drug, which they then compare to thatof the pioneer drug. The generic version must deliver the same amountof active ingredients into a patient's bloodstream in the same amountof time as the pioneer drug.

A Supplemental NDS (New Drug Submission) (SNDS) must be filedby a brand-name or generic manufacturer if certain changes are made toan already-authorized product. Such changes might include:

- The dosage form or strength of the drug
- The formulation
- The method of manufacture, labeling or recommended route of administration.
- An expansion of the claim or conditions of use for the drug.

A DIN (Drug Identification Number) application mustbe filed for those products that do not meet the definition of a 'newdrug'. This happens when a substance has been sold in Canada for longenough and in sufficient quantities to have established its safety andeffectiveness for use as a drug.

The review process

If, at the completion of a new drug review, HPFBconcludes that the benefits outweigh the risks and that the risks canbe mitigated and/or managed, the product is issued a Notice ofCompliance (NOC) and aDrug Identification Number (DIN (Drug Identification Number)),as required in the Food and Drugs Act and Regulations. This allows themanufacturer to sell the product in Canada.

Filing an NDS as opposed to an NDS is less demanding for ageneric drug manufacturer because many of the safety and efficacyconcerns were addressed when the reference product was approved. Thegeneric product goes through a screening process, which HPFBtries to complete in 45 days. If anything is unclear in the file, themanufacturer has 15 days to clarify the issue. If it fails to clarify,a Notice of Non-Compliance (NON (Notice of Non-Compliance))is issued and the company has three months to reply. Also, if thereare deficiencies in the file, a Notice of Deficiency (NOD) is issued, although this isnot very common.

If the submission is complete, it enters the formal review process,which HPFB (Health Products and Food Branch (Health Canada))attempts to complete in 180 days (it may take much longer). Threereviews are performed to determine if the drug complies with the Foodand Drugs Act :

- Chemistry and manufacturing
- Safety and efficacy
- Product information.

If, on completing its review, HPFBfinds that the submission does not comply with the requirements of theFood and Drugs Act and Regulations, it will issue a Noticeof Non-Compliance (NON (Notice of Non-Compliance)).This notice outlines HPFB'sconcerns and generally asks for more information. The manufacturermust respond by a specified date. If the submission does comply, a NOC is issued.

The patented medicines (notice of compliance) regulations

The Patented Medicines (Notice of Compliance) Regulations (NOC Regulations) [107] are the link between the Patent Act [108] and the review process under the Food and Drugs Act and Regulations. The dual purpose of the NOC Regulations is to ensure that, on the one hand, the timely access to Canadians of lower cost medicines and, on the other hand, the "early working" exception to patent infringement is not abused by second entry manufacturers.

The Therapeutic Products Directorate of Health Canada maintains a patent register consisting of patent lists submitted by first persons (innovators). The Patent Register [109] is an alphabetical listing of medicines and the associated patents, patent expiry dates and other related information, established in accordance with the NOC Regulations. When a generic or second entry manufacturer seeks approval of a drug in Canada based on a previously approved drug, itmust address all patents listed on this register concerning that drug.

After a generic manufacturer files an NDS on a drug covered by a patent on the Patent Register, and while the safety and efficacy are being reviewed, the applicant must either:

- Advise HPFB that it will accept that the NOC will not be issued until the patent expires or
- File a statement claiming that the person who filed the patent list is not the patent owner (or acting with the owner's consent) or
- File a statement that the patent has either expired, is not valid, or is not infringed (a Notice of Allegation, or NOA). [110]

The NOA (Notice of Allegation) must be served onthe person who submitted the patent list (generally the holder of theoriginal NOC). Thatperson then may, within 45 days, apply for a court order prohibiting HPFBfrom issuing an NOC for thesecond-entry (generic) product.

If it receives notice of such a court application, HPFBcannot issue a NOC for 24months, or until the court makes a determination regarding theallegations in the NOA (Notice of Allegation),whichever comes first. The court may shorten the 24-month period orextend it if the parties consent, or if the court finds that one orboth of the parties has failed to reasonably co-operate in expeditingthe application.

The generic manufacturer must address all patents on the patent list given by the patentee to Health Canada. Prior to October 2006, a patentee was able to re-start the 24 month automatic stay by listing new patents for formulations or uses after a generic company filed its ANDS. This practice would extend market exclusivity long after the initial patent or patents on it had expired.

The new patents could be added at any time, and in some cases, new patents were added days before the original patent on the active ingredient expired. Under the October 2006 amendments to the NOC Regulations, a generic manufacturer who files a submission or supplement for an NOC for ageneric version of an innovative drug need address only the patents on the Register as of that filing date. Patents added to the register after that filing date would not have to be addressed. The register is "frozen" for the generic manufacturer. [111]

If the person who submitted a patent list applies for a court order, an NOC cannot beissued for the generic product until either:

- The 24 month stay expires or
- The patent expires or
- The court declares there would be no patent infringement or
- The court application is withdrawn, discontinued or dismissed. [112]

If the patentee wins the case, the NOC cannot beissued until the final patent expires. If the generic wins, an NOC can beissued as soon as Health Canada has completed its review for safetyand efficacy.

Filing and management of drug submissions

All drug submissions must be accompanied by:

- A completed drug submission application form
- A submission evaluation fee form
- A copy of the proposed label(s)
- The appropriate drug submission certification form.

New drugs must have a copy of the product monograph. Drug submissionsare processed according to the Management of Drug SubmissionsPolicy, which also identifies the performance targets for reviewtime frames for different types of submissions.

The Submission Evaluation Fees Guide identifies theevaluation fee and the timing of payment for different types ofpre-market drug submissions. Fees are charged for the followingservices linked to the regulation of drugs:

- Drug Submission Evaluation
- Drug Master File Registration
- Issuance of Export Certificates (for non-controlled drugs).

In addition to the fee for evaluating the safety, efficacy and qualityof a product, HPFBlevies other user fees [113] for drug therapeuticproduct regulatory activities:

- Fees for maintaining the right to market a product (an annualfee must be paid for each Drug Identification Number (DIN) that pertains to adrug)
- A fee for an establishment license that certifies the type ofoperations and category of products that the establishment isauthorized to handle.

Product labelling

Once a drug is approved for the Canadian market, it must be packagedand distributed with information that will help consumers make aninformed choice about its use. The general labeling requirements areoutlined in Part C of the Food and Drug Regulations.

Good Manufacturing Practices (GMP (Good Manufacturing Practices))

All drugs marketed in Canada are subject to good manufacturingpractices (GMP (Good Manufacturing Practices)) asoutlined in Part C of the Food and Drug Regulations. The GMP and establishmentlicensing requirements apply to drugs in dosage form and to most bulkintermediates. The Food and Drug Regulations make itmandatory for fabricators, packagers/labelers, importers anddistributors to have detailed information available about drugproducts for sale in Canada. All facilities involved in theseactivities are licensed and inspected by Health Canada to ensure thatthe GMP (Good Manufacturing Practices) standardsare met.

Environmental assessment

All products regulated under the Food and Drugs Act aresubject to the *Canadian Environmental Protection Act*, 1999 [114] and the New Substances Notification Regulations. [115] Pharmaceuticals, cosmetics, veterinary drugs, food additives,novel foods, biologicals (including genetic therapies),radio-pharmaceuticals, medical devices, and natural health productsare all included. Before importing or manufacturing a new substance inCanada, importers or manufacturers must provide additional data toHealth Canada so that an environmental assessment can be conducted.

Establishment licenses

Establishment licenses ensure that manufacturers comply with goodmanufacturing practices (GMP (Good Manufacturing Practices))or equivalent standards for drugs and natural health products. Allestablishments that fabricate, package, label, import, distribute orwholesale these products, or operate a testing laboratory for them,must have an establishment license, unless they are expressly exemptedunder the Food and Drugs Act and Regulations.

HPFB (Health Products and Food Branch (Health Canada))also inspects manufacturing plants and other sites where productscovered under the Food and Drugs Act are handled to verifycompliance with regulatory requirements. Establishment licenses,issued by Health Canada, are renewed on a yearly basis. Establishmentlicense holders are inspected every three years. Traditionalmedicines, homeopathic preparations, and vitamin and mineralsupplements, when in dosage form and intended for self-medication, arecurrently exempt from this requirement.

Imported products

It is mandatory that a person in Canada be responsible for importeddrug products. Importers usually must hold an establishment licenseand have evidence available that the imported products meet Canadian GMP or equivalent standards.

Where a drug is registered in the name of a company not locatedin Canada, the name of the importer and the business address of theperson in Canada responsible for its sale must appear on the inner andouter labels of the drug. Importers must provide evidence that theirproducts meet the same standards as those manufactured domestically,before they can become available in Canada. This may involveinspection of specific incoming shipments and close cooperation withthe Canada Border Services Agency.

An establishment license is not required if:

- The importer is a practitioner, pharmacist or a person underthe supervision of a practitioner
- The drug is imported for a prescription
- The drug is not commercially available in Canada.

To determine whether imported drugs meet Canada's GMP regulatoryrequirements, Health Canada uses reports from its own inspectors orfrom recognized partner countries under the terms of MutualRecognition Agreements (MRA (Mutual Recognition Agreement)) [116] and the Pharmaceutical Inspection Cooperation Scheme (PIC/S).It also uses inspection reports from the United States Food and DrugAdministration.

The use of inspection reports from recognized partner countries isbased on a rigorous process that has established equivalency of both GMP standards andcompliance inspection procedures and reports between the two countries.

Distribution

Schedule F to the Food and Drug Regulations identifies thosedrugs that are authorized for sale on condition that they areprescribed by a physician. The distribution of drug products for humanuse is governed by the Provinces.

Compliance and enforcement

HPFB (Health Products and Food Branch (Health Canada))has inspectors who verify compliance with the Food and DrugsAct and Regulations. Where necessary, they take steps to enforce theprohibitions outlined in these laws. Under the authority of the Foodand Drugs Act, inspectors can enter and inspect places where drugsare manufactured, prepared, preserved, packaged or stored. If anynon-compliance is found, appropriate actions are taken.

Appendix 2: Data description

The data in this study refer only to prescription drugs sold inCanada. Non-prescription or over-the-counter (OTC) drugs are excluded. Brand-nameand generic drug-product data were sourced from IMS Health andBrogan Inc. (Incorportated)

IMS (Intercontinental Medical Statistics) health —Canadian drug store and hospital purchases audit

Canadian Drug Store and Hospital Purchases Audit (CDH)from IMS (Intercontinental Medical Statistics)collects data on dollar value and unit volume of pharmaceuticalproducts purchased by retail pharmacies and hospitals, from arepresentative sample of over 2,000 drugstores and 563 hospitals.

The sample data is projected to the universe of drugstores andhospitals to reflect all purchases in Canada. Drug purchase data arecollected electronically and include the following data items:corporation/manufacturer, molecule/chemical, product name, launchdate, strength, package size, dollar sales, units, and prescriptions.Data take into account the purchases of drugstores and hospitalsregardless of whether purchases were made directly from manufacturersor through wholesalers. Therefore, it includes markup by wholesalersfor the volume moving through wholesalers.

The data set used in this report contains information on 108molecules on the Canadian market that lost patent protection between2001 and 2006. For each strength and dosage format, byprovince/region, on a monthly basis, the following information wasavailable: molecule name, product name, therapeutic class level three,manufacturer,

strength, product form, launch date, number ofprescriptions, number of extended units purchased and price ofpurchase.

The extended unit may be pills (for oral solids), millilitres(for liquids), doses (for some inhalers) and grams (for powders).

Brogan group — Public and private drug plans database

Provincial data from Brogan Inc. (Incorportated)covers British Columbia, Alberta, Manitoba, Ontario, Quebec, NewBrunswick, Nova Scotia, Prince Edward Island, and Newfoundland andLabrador. Brogan provincial data provide information on drugutilization metrics for molecules available in Canada whose patentexpired between 1998 and 2005.

The data set used in this report contains information on OTC and prescription drugs for 283molecules available in Canada that lost patent protection between 1998and 2005. Of these, 200 molecules were sold by prescription only. Foreach molecule, by province, the following information was available: DIN, molecule name, productname, therapeutic class, manufacturer, strength, product form, patentexpiry date for branded drugs, NOC issuedate, launch date, formulary listing date, formulary listing price,number of claims, number of units dispensed and cost of claims.

In every province except Newfoundland and Labrador, the costelement includes the drug ingredient cost and the pharmacy mark-up. InNewfoundland and Labrador the cost consists of: drug ingredient cost +pharmacy mark-up + pharmacy dispensing fee (for some plans) — patientco-payment.

The average pharmacy mark-up was 7% in Alberta, British Columbiaand Manitoba, 8% in New Brunswick and Nova Scotia, 15% in Newfoundlandand Labrador, 10% in Ontario, 12.95% in Prince Edward Island and up to9% in Quebec. In Saskatchewan the pharmacy mark-up is 30% for a drug cost up to $6.30, 15% for a drug cost between $6.31 and $15.80, and10% for a drug cost of $15.81 to $200.00, up to a maximum of $20.00for drug cost over $200.00. The private plans allowed for an averagemark-up of 10%.

The following version of each provincial formulary was used toobtain information on formulary list prices.

Table 16. Sources of provincial formulary prices

AB (Alberta)	Alberta HWDBL Full list, January 2007 and Alberta Additions, March 2007
BC (British Columbia)	Up to Bulletin of March 21 2007
MB (Manitoba)	Manitoba Interchangeable Formulary, December 2006
NL	Interchangeable Drug Formulary, March 2007
NB (New Brunswick)	New Brunswick: MAP List, March 2007
NS (Nova Scotia)	MAC List, July 2006 and update MAC, February 2007
PEI (Prince Edward Island)	MAC List, May 2006
ON (Ontario)	ODB (Ontario Drug Benefit) Edition 39 and updates, March 2007
Source : Brogan Inc. (Incorportated)	

QC (Quebec)	Liste de Medicaments, February 2007
SK (Saskatchewan)	Formulary of February 2006 and many bulletins until January 2007
Source : Brogan Inc. (Incorporated)	

Appendix 3: List of acronyms

AB (Alberta): Alberta

AG (Authorized (or licensed) Generics): Authorized (or licensed) Generics

NDS: Abbreviated New Drug Submission

API (Active Pharmaceutical Ingredient): Active Pharmaceutical Ingredient

ASHP (American Society of Health-System Pharmacists): American Society of Health-System Pharmacists

BC (British Columbia): British Columbia

CAPDM (Canadian Association for Pharmacy Distribution Management): Canadian Association for Pharmacy Distribution Management

CDH (Canadian Drug Store and Hospital Purchases Audit): Canadian Drug Store and Hospital Purchases Audit

CGPA (Canadian Generic Pharmaceuticals Association): Canadian Generic Pharmaceuticals Association

CHA (Canada Health Act): Canada Health Act

CIBC (Canadian Imperial Bank of Commerce): Canadian Imperial Bank of Commerce

CIHI (Canadian Institute for Health Information): Canadian Institute for Health Information

CMDB (Canadian Management Information Systems Database): Canadian Management Information Systems Database

DC (Distribution Channel): Distribution Channel

DIN (Drug Identification Number): Drug Identification Number

DND (Department of National Defense): Department of National Defense

GJC (Groupe Jean Coutu): Groupe Jean Coutu

GMP (Good Manufacturing Practices): Good Manufacturing Practices

GPO (Group Purchasing Organizations): Group Purchasing Organizations

HBM (Health Benefit Managers): Health Benefit Managers

HPA (Health Plan Administrator): Health Plan Administrator

HPFB (Health Products and Food Branch (Health Canada)): Health Products and Food Branch (Health Canada)

ICES (Institute for Clinical Evaluative Sciences): Institute for Clinical Evaluative Sciences

IDA (Independent Druggists' Association): Independent Druggists' Association

IG (Independent Generic): Independent Generic

IMS (Intercontinental Medical Statistics): Intercontinental Medical Statistics

IPD (Independent Pharmacy Distributors): Independent Pharmacy Distributors

IT (Information Technology): Information Technology

IV (Intravenous): Intravenous

MB (Manitoba): Manitoba

MRA (Mutual Recognition Agreement): Mutual Recognition Agreement

NB (New Brunswick): New Brunswick

NDS (New Drug Submission): New Drug Submission

NIHB (Non-Insured Health Benefits): Non-Insured Health Benefits

NL (Newfoundland & Labrador): Newfoundland & Labrador

NOA (Notice of Allegation): Notice of Allegation

NOC: Notice ofCompliance

NOD (Notice of Deficiency): Notice of Deficiency

NON (Notice of Non-Compliance): Notice of Non-Compliance

NPS (National Pharmaceutical Strategy): National Pharmaceutical Strategy

NS (Nova Scotia): Nova Scotia

OCOTH (Ontario Council of Teaching Hospitals): Ontario Council of Teaching Hospitals

OCP (Ontario College of Pharmacists): Ontario College of Pharmacists

ODB (Ontario Drug Benefit): Ontario Drug Benefit

OECD (Organization for Economic Co-operation and Development):Organization for Economic Co-operation and Development

ON (Ontario): Ontario

OTC (Over The Counter): Over The Counter

PBM (Pharmacy Benefit Manager): Pharmacy Benefit Manager

PBM (Pharmacy Benefit Manager)/HBM: Pharmaceutical/HealthBenefit Managers

PDCI (Palmer D'Angelo Consulting Incorporated): Palmer D'Angelo Consulting Inc. (Incorportated)

PEI (Prince Edward Island): Prince Edward Island

PIC/S (Pharmaceutical Inspection Cooperation Scheme): Pharmaceutical Inspection Cooperation Scheme

NOC: PatentedMedicines Notice of Compliance

PBPRB (Patented Medicines Price Review Board): Patented Medicines Price Review Board

POS (Point of Sale): Point of Sale

P&T (Pharmacy and Therapeutics): Pharmacy and Therapeutics

QC (Quebec): Quebec

RCMP (Royal Canadian Mounted Police): Royal Canadian Mounted Police

R&D (Research and Development): Research and Development

RHA (Regional Health Authority): Regional Health Authority

RFI (Request for Information): Request for Information

RFP (Request for Proposal): Request for Proposal

Rx (Prescriptions): Prescriptions

SK (Saskatchewan): Saskatchewan

SNDS (Supplemental New Drug submission): Supplemental New Drug submission

TPD (Therapeutic Products Directorate): Therapeutic Products Directorate

TPP (Third Party Providers): Third Party Providers

US (United States): United States

Footnotes

1 In comparison,hospitals accounted for 29.8% of the forecasted $148 billion spent onhealth care in Canada in 2006. See CanadianInstitute for Health Information (CIHI),"Drug Expenditure in Canada, 1985-2006".

2 Retailpharmacy expenditures were $15.74 billion and hospital pharmacyexpenditures on drugs were $2.08 billion. See IMS " NewsRelease for 2006 Canadian Pharmaceuticals Review"

3 Source: IMS Health available

4 Ibid.

5 PBPRB, June 2006, "Canadian and Foreign Price Trends". Other studies finding Canadian generic drugs prices to be high in comparison toother countries include:
i) PalmerD'Angelo Consulting Inc, August 2002, "Generic Drug Prices: ACanada US (United States) Comparison" PDCI ReportSeries;
ii) PBPRB, November 2002, "A Study of the Prices of the Top Selling Multiple Source Medicines in Canada";
iii) BrettSkinner, August 2004, "Generic Drugopoly: Why Non-Patented¨ Prescription Drugs Cost More in Canada than in the UnitedStates and Europe";
iv) BrettSkinner, February 2005, "Canada's Drug Price Paradox: TheUnexpected Losses Caused by Government Interference in PharmaceuticalMarkets"; and
v) PBPRB, October 2006, "Trends in Canadian Sales and Market Structure".

6 Federal/Provincial/Territorial Ministerial Task Force, June 2006, "NationalPharmaceuticals Strategy Progress Report".

7 Available at:http://healthycanadians.gc.ca/index-eng.php. Participants in the NPS (National Pharmaceutical Strategy) include thefederal government and all provinces with the exception of Quebec.

8 Non-patenteddrugs include brand-name drugs that lost patent protection as well asgeneric drugs. The June 2006 PBPRB reportreferred to above was the first of these quarterly reports.

9 NationalPharmaceuticals Strategy Progress Report, June 2006, supra, note 7.

10 The TransparentDrug System for Patients Act 2006, S.O. 2006, c. 14, passed third andfinal reading in the Legislative Assembly of Ontario on June 19, 2006and received royal assent on June 20, 2006. Certain provisions of theAct came into force upon royal assent and the balance came into forceon October 1 st, 2006.

11 Priceregulation in Ontario and Quebec is examined in more detail in Chapter 3.

12 Joseph D'CruzJ., Walid Hejazi W. and G. eorge Fleischman, 2005,“Comparisons of Retail Prices of Generic Prescription Drugs inCanada vs. United States: A Comprehensive Study”, available onthe Canadian Generic Pharmaceuticals Association Web site

13 For thepurpose of this analysis, we use the term manufacturer, even though acompany did not manufacture but just distributes the product inCanada. According the Food and Drug Regulations, C.R.C., c. 870, a manufacturer of a drug is not necessarily the company that makesthe product, but the company to which the product is registered at thetime of approval.

14 Recentlybought by Mylan Laboratories Inc. (Incorportated)as part of its acquisition of Merck KGaA's generic business,Genpharm's parent company.

15 Recentlybought by Hospira Inc. (Incorportated) as part ofits acquisition of Mayne Pharma Limited, Mayne Pharma Canada's parentcompany.

16 Recentlybought by Sun Pharmaceutical Industries Limited, an Indianpharmaceuticals company.

17 While NOCRegulations prevent a firm from using the process to delay a genericversion of the original formulation when the brand-name drug losespatent protection, it does not prevent a brand-name firm frommarketing "new and improved" formulations.

18 The approvalprocess is described in more detail in the next section.

18 Licensing mayalso take place between two generics manufacturers.

20 Sunk costsare costs that are non-recoverable once spent.

21 The genericfirm may undertake its own clinical trials instead of conductingbio-equivalence studies. In practice, however, showing bio-equivalenceis much less expensive and generic firms almost always choose thispath. See Bristol-Myers Squibb Co. v. Canada (AttorneyGeneral), 2005 SCC 26.

22 In the caseof topical products, the NOCapplication cannot be submitted until after the clinical trial resultsare available. Once the NOCapplication has been submitted, approval of topical prescriptionproducts takes from six to eight months.

23 In asubsequent 2006 decision, the Supreme Court of Canada held that ageneric manufacturer is only required to address patents on the PatentRegister that are relevant to the actual comparator drug. In addition,the generic manufacturer is not required to address patents issuedafter the NOA (Notice of Allegation) was made(since the generic manufacturer could have received no benefit fromthose patents). See AstraZeneca Canada Inc. v. Canada (Minister of Health),[2006] S.C. (Supreme Court)J. No. (Number) 49.

24 SOR/93-133, s. (section) 4.

25 Ibid., s. (section) 8(4).

26 In additionto patents related to the active ingredient(s), formulation andprocess patents are listed by brand-name companies on the PatentRegister. Typically, the patents on active ingredients expire first,thus giving generic manufacturers the possibility to enter the marketby challenging the remaining patents prior to their expiration.

27 It has beensuggested that this could result in there being limited incentive tochallenge patents. While this may be unlikely to be the case forpopular drugs, it could affect the supply of generics for drugs withlimited use and/or smaller sales. Examining this matter is anempirical issue beyond the scope of this study.

28 As developedin section 5.A., there may be limited exceptions for medical reasons.

29 Effectivesupply chain management is another key consideration. Pharmacies wantto be sure that a drug is available to be dispensed to patients when needed.

30 In 2004, theprovince took four different legal actions before the Superior courtof Quebec against four manufacturers of generic drugs (Apotex,Novopharm, Pharmascience and Ratiopharm) alleging that they had,between 2000 and 2003 given approximately 37% of illegal rebates anddiscounts. See for example the decision of the Superior Court ofQuebec dated July 27, 2004, with respect to Quebec(Régie de l'Assurance-maladie) c. Pharmascience Inc., 2004 CanLII 4667 (QC C.S.). See also respective files of the Superior court of Quebec no500-17-015571-030, no 500-17-015460-036 and no 500-17-015406-039. InQuebec, Bill 130 adopted in 2005 and the Quebec Drug Policy publishedin February 2007 have set the stage for future "professionalallowances" similar to Ontario's to be provided. However, they are notyet included in regulations.

31 Publicsources that put the average rebate at 40% include: i) CIBC WorldMarkets, "2003 Investors' Guide To The Canadian DrugstoreIndustry", May 26, 2003 and ii) Ontario Ministry of Health andLong-term Care, "Challenges Facing Ontario's Drug System And HowWe Are Responding To Them", available at: www.health.gov.on.ca/english/media/news_releases/archives/nr_06/apr/bg_041306_a.pdf. Theimplications of rebates for pharmacies are discussed in section 4.A.2.

32 Aidan Hollisand Bryan Liang, "Assessing the effects of authorized generics onconsumer prices" Journal of Biolaw and Business,forthcoming.

33 The issue ofauthorized generics and their role in providing competition toindependent generics is being considered by the US Federal Trade Commission, which isconducting a related market study.

34 A drug marketwas defined for the purpose of the study as a unique combination ofmolecule and dosage form.

35 These resultsare partial, based on a limited set of drugs. More information (e.g. abroader sample size, information on terms of contract and market size)is needed to assess fully the impact of AG on thecompetitive framework for generic drugs.

36 While suchbundling is not inherently anti-competitive, bundling can haveanti-competitive effects in certain circumstances, for example, whereit is used by a dominant firm to exclude competitors from the marketresulting in a substantially lessening of competition.

37 Source:Canadian Generic Pharmaceuticals Association (Canadian GenericPharmaceuticals Association).

38 Further, suchan analysis would require detailed information regarding whichproducts should be included in the relevant markets and relatedbarriers to entry. For example, the mere finding that a non-patentedproduct has one or a small number of suppliers, is not adequate toconclude that is not subject to competition.

39 A set of 32molecules for which the first generic entered between January 2002 andJuly 2006 was analyzed. Brand sales in the year prior to the firstgeneric entrant are considered.

40 PBPRB, October 2006 and June 2006, supra, note 6.

41 Sources:interviews with sector participants, company web sites and otherpublic sources.

42 Source CAPDMIndustry Trend Report: Focus on Retail Pharmacy, December 2006.

43 See IMS News Releasefor “2006 Canadian Pharmaceuticals Review“.

44 Thesedefinitions are taken from McKesson Canada Trends and Insights Report,2006, pp. (pages) 12–13.

45 Note thatnumbers do not add up to 100 due to rounding.

46 Independentsor banner store pharmacy owners that have 5 or more stores areconsidered to be pharmacy chains.

47 Source: CAPDM“2006 Pharmacy Who's Who” and the Rexall Group atwww.Rexall.ca. Note that these numbers do not include pharmacies using independent pharmacy banner programs operated by McKesson Canada. Pharmacies subscribing to these programs number in excess of 650 across Canada.

48 Totalprovincial retail pharmacy numbers are as provided by IMS Health for May 2006.

49 CIBC Report, supra, note 38, p. (page) 30.

50 Available at:www.pharmacygateway.ca, p. (page) 31. Numbers are for pharmacies and do notnecessarily cover all sales in the relevant stores.

51 Within thelast year, some prescribing authority has been granted to pharmacistsin various provinces, with more jurisdictions contemplating some formof prescribing role for the pharmacists. Provincial interchangeabilitylaws, policies and regulations and other relevant aspect of provinciallegislation and pharmaceutical plans are developed in section 5.A.

52 See, forexample, the comments to the Standing Committee on Social Policy on TransparentDrug System For Patients Act, 2006, by Pharmasave Ontario and theCoalition of Ontario Pharmacy, May 29, 2006.

53 As discussedfurther in the public reimbursement discussion below, under Ontariolegislation the maximum price for generic drugs reimbursed by theprovinces was 70% of the brand equivalent price for the first genericproduct on the market, and 90% of the first generic product's pricefor subsequent generics. The numbers used for this example are basedon the maximum cost of a second and subsequent generic products on the market.

54 The numbersused in the table reflect allowable mark-ups and dispensing fees inOntario prior to the creation of the Transparent Drug SystemFor Patients Act, 2006. Allowable mark-ups may vary significantly inother provinces. Prior to June 2006, Ontario allowed a maximum mark-upof 10% but this has since been reduced to 8%.

55 Dispensingfees can also vary substantially from province to province. For alisting of public drug plans allowable dispensing fees and mark-upssee CIHI (Canadian Institute for Health Information),supra, note 1, Appendix.

56 The spreadbetween the return to sales of the generic drug versus the brand drugmay be greater where allowable mark-ups are not contingent on thirdparty distribution as these costs are normally absorbed by genericmanufacturers but not suppliers of brand products.

57 The relatedQuebec policies are discussed in section 5.A.

58 Ministerialproposal no (number) 24 of the Quebec February 2007 Drug Policy would allowprofessional allowances similar to those permitted in Ontario.

59 R.S.C 1985, c. C-6.

60 Ringold D.J.,Santell J.P., Schneider P.J., Arenberg S. (1999), “ASHPnational survey of pharmacy practice in acute care settings:prescribing and transcribing. American Society of Health-SystemPharmacists”, American Journal of Health System Pharmacy, 56,142-157.

61 RHAs have been establishedin all provinces except Ontario. RHAs are described in Organizationfor Economic Cooperation and Development, Competition in theProvisions of Hospital Services, October 27, 2006, pp. (pages) 115 –121.

62 www.medbuy.ca.

63 The unitinvoice prices compared were calculated based on retail pharmacies'and hospitals' drug acquisition costs and do not include off invoicerebates or discounts.

64 Theremaining 2% of the population that is not covered is concentratedamong working age persons in the provinces of Newfoundland andLabrador, Nova Scotia, New Brunswick and Prince Edward Island.

65 Coverage ofpersons under public and private drug plans is as reported in Paris,V. And Docteur, E (2006), "Pharmaceutical Pricing AndReimbursement Policies In Canada", OECD,Directorate For Employment, Labour And Social Affairs -HealthCommittee, DELSA/HEA/WD/HWP (2006) 4, p. (page) 17.

66 CIHI, supra, note 2, pp. (pages) 9-11.

67 Ibid. More than 80% of the expenditures under social security funds areprovided under the Quebec Drug Insurance Fund for residents who arenot otherwise covered by provincial programs or by private healthinsurance.

68 Public plansmay also provide for drugs to be reimbursed that are not listed onformularies in certain circumstances.

69 Differentinformation may be required for authorized generics. For example, inlieu of bio-equivalence data, letters may be supplied from themanufacturer of the generic and the manufacturer of the brand drug(possibly the same manufacturer for both) stating that the generic ismanufactured under the identical master formula, and manufacturing andquality control specifications as the brand product.

70 For someprovinces (Prince Edward Island, Nova Scotia), the review ofapplications for listing may take as little as a month. However, inother provinces, the formulary review and update process may be lessfrequent, for example on a quarterly or semi-annual basis.

71 See Paris andDocteur (2006), supra, note 65, p. (page) 18.

72 See, FederalHealthcare Partnership 2007-2010 Business Plan, p. (page) 26.

73 ForSaskatchewan, see The Pharmacy Act, 1996, S.S, 1996, c.P-9.1 at sections 54-55. For Newfoundland and Labrador, see PharmaceuticalServices Act, S NL (Newfoundland & Labrador) 2002,c. P-12.01 at sections 9 and 21. For P.E.I., see the InterchangeableDrug List Regulations (EC 287/05) at sections 15-16.

74 For Ontario,see Drug Interchangeability and Dispensing Fee Act, R.S.O.1990, c. P-23 at sections 4(1) and 5. For Quebec, see Loi sur lapharmacie L.R.Q., chapitre P-10, at s. 21. For Nova Scotia, see PharmacyAct, S.N. 2001, c. 36 at section 28. For Alberta, see PharmaceuticalProfession Act, R.S.A. 2000, c. P-12. For New Brunswick, see PharmacyAct, S.N.B. 1983, c. 100 at section 39. For,B.C. see Pharmacists,Pharmacy Operations and Drug Scheduling Act, R.S.B.C. 1996, c. 363 at section 30.

75 Theexceptions are Quebec and Nova Scotia. In Nova Scotia, licensurerequirements ensure that all pharmacists have liability coverage wheninterchanging legally allowable substitutions.

76 Theseprovisions came into force on October 1st, 2006.

77 Lapolitique du medicament, p. (page) 40. These price caps are due to be putinto effect in February 2008. However, Quebec's 'most favoured nation'clause, discussed below, means that Quebec will also benefit from thenew Ontario price caps for generic drugs under t he Transparent DrugSystem for Patients Act 2006.

78 Lapolitique du medicament (Quebec Drug Policy), edited by La Directiondes communications du ministère de la Santé et desServices sociaux, see section entitled L'établissementd'un prix juste et raisonnable des médicaments, p. (page) 7. Notethat this policy also applied to wholesalers' mark-ups.

79 Thisframework is due to come into effect in February 2008.

80 The termmaximum allowable cost has, in some provinces, been applied acrosstherapeutically similar, but not necessarily interchangeable genericdrugs. This discussion refers only to cases involving bio-equivalentinterchangeable drug products.

81 In Quebec,however, this policy does not come into effect unless the originalbrand product has been on the provincial formulary for 15 years.

82 However,Quebec allows limited rebates for rapid payment.

83 Exceptionsmay be allowed for medical or supply reasons.

84 AuQuébec, la legislation concernant le remboursement desmédicaments génériques fait reference à laclause du meilleur prix consenti au Canada.

85 RegulationRespecting the Conditions on which manufacturers and wholesalers ofmedications shall be recognized, R.Q. c. A-29.01, r.1.1

86 Ibid., see Schedule I.

87 PharmaceuticalServices Act, chapter P-12.01 at section 23.

88 The pricespartially reflect price changes implemented in October 2006 caused bythe lowering of Ontario's maximum ODB (Ontario Drug Benefit)formulary generic drug prices to 50% of the brand product price.

89 The sampledoes not include generic drug products obtained under the SaskatchewanStanding Offer Contract process, which is discussed further below.

90 Fordiscussion of these concerns, see, for example, Paris and Docteur(2006), supra, note 65, pp. (pages) 35-38.

91 It may benoted that all of Saskatchewan's 91 standing offer contracts aresupplied by two companies, Dominion Pharmacal and Nu-Pharm, which sellthese drugs exclusively in the province.

92 In the caseof Ontario, prices are based on the revised maximum formulary priceformula implemented in January 2007.

93 See CIHI, supra, note 2.

94 Paris andDocteur (2006), supra, note 65, p.18.

95 Thesecompanies may also provide related services to provincial drug plans.

96 CIBC Report, supra, note 38, p. (page) 61.

97 Higherprivate plan prices may occur, for example, where the price of brandand generic drugs on a provincial formulary is frozen over time butthe price for other parties is allowed to increase.

98 See FederalTrade Commission, Pharmacy Benefit Managers: Ownership ofMail-Order Pharmacies, August, 2005, p. (page) 9 which reports maximumallowable costs to plan sponsors of generic drugs obtained through PBMs of, on average, 62% offthe manufacturer's wholesale price.

99 Quebec hasalso established maximum price regulations. However they are not dueto come into effect until February 2008 and their effect has beenmitigated by the revised Ontario formulary prices that will beautomatically adopted under Quebec's formulary policies.

100 While theyare not inherently anti-competitive, in certain circumstances, such aswhere they are used by a dominant firm to induce exclusive supply,rebates may have anti-competitive effects.

101 However,Quebec's public plan formulary prices are due to be adjusted inFebruary 2008 to reflect the new Ontario maximum price level.

102 R.S.C 1985, c. F-27, available at http://lois-laws.justice.gc.ca/fra/lois/F-27//.

103 C.R.C., c. 870,available at http://lois-laws.justice.gc.ca/fra/lois/F-27//.

104 Foodand Drugs Act, s. 2.

105 The DIN is an eight-digitnumber located on the label of prescription and non-prescription drugproducts n authorized for sale in Canada.

106 See http://www.hc-sc.gc.ca/index-eng.php.

107 SOR/93-133,available at http://laws-lois.justice.gc.ca/eng/.

108 R.S.C 1985, c. P-4.

109 TheTherapeutic Products Directorate has developed a web-accessible version of thePatent Register.

110 NOCRegulations, s. 5.

111 Ibid., s. 5(4).

122 Ibid., s. 7.

113 Moreinformation.

114 S.C. 1999,c. 33.

115 SOR 2005/247and SOR 2005/248.

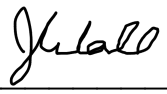
116 Canada hasestablished MRA (Mutual Recognition Agreement) withAustria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland,Ireland, Italy, Liechtenstein, Netherlands, Norway, Portugal, Spain,Sweden, Switzerland, and the United Kingdom. An MRA is also beingfinalized with Australia. The Pharmaceutical Inspection CooperationScheme members include the MRA (Mutual Recognition Agreement)countries listed above, as well as: Czech Republic, Hungary, Malaysia,Romania, Singapore, Slovak Republic and Latvia.

Date modified:
2022-01-20

ontact the Competition Bureau

Exhibit “S5”

This is Exhibit “S5” referred to in the Affidavit of Emily Seaby, sworn before me this 26th day of July, 2024.



A Commissioner for Taking Affidavits, etc.
Jon Wall

Abuse of Dominance

Enforcement Guidelines

Canada

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Preface

The Competition Bureau (the "Bureau"), as an independent law enforcement agency, ensures that Canadian businesses and consumers prosper in a competitive and innovative marketplace. Headed by the Commissioner of Competition (the "Commissioner"), the Bureau investigates anti-competitive practices and promotes compliance with the laws under its jurisdiction, including the *Competition Act* (the "Act").[1]

Competition among firms underpins a robust economy, incentivizing the creation of value and rewarding entrepreneurship and innovation. When firms compete on the merits, market forces generally deliver the most efficient and beneficial economic outcomes for society.

In some cases, however, dominant firms can frustrate this process by engaging in conduct that undermines competitive market forces, leading to inefficient outcomes. In these rare circumstances, the Bureau may rely upon the abuse of dominance (and other) provisions of the Act to address specific conduct and restore the competitive process.

These guidelines describe the Bureau's general approach to enforcing the abuse of dominance provisions (sections 78 and 79 of the Act). They supersede all previous guidelines and statements of the Commissioner or other Bureau officials regarding the administration and enforcement of the Act's abuse of dominance provisions.

The Abuse of Dominance Enforcement Guidelines do not replace the advice of legal counsel and are not intended to restate the law or to constitute a binding statement of how the Commissioner will proceed in specific matters. The decisions of the Commissioner and the ultimate resolution of issues will depend on the particular circumstances of the matter in question.

Throughout these guidelines, judicial decisions are referenced by abbreviations. Full citations may be found at the end of the document. Any reference to jurisprudence represents the Bureau's interpretation of the law.

Final interpretation of the law is the responsibility of the Competition Tribunal (the "Tribunal") and the courts.

1 RSC 1985, c C-34.

Table of contents

Executive Summary

i. Abuse of a dominant position occurs when a dominant firm or a dominant group of firms engages in a practice of anti-competitive acts, with the result that competition has been, is, or is likely to be prevented or lessened substantially in a market. Simply being a dominant firm, or even a monopoly, does not in and of itself engage the abuse of dominance provisions of the Act.

ii. Three elements must be established to constitute an abuse of dominance under section 79 of the Act:

- one or more persons must substantially or completely control a class or species of business throughout Canada or any area thereof;
- that person or those persons must have engaged in (within the previous three years) or be engaging in a practice of anti-competitive acts; and
- the practice must have had, be having or be likely to have the effect of preventing or lessening competition substantially in a market.

iii. To evaluate the first element, dominance, the Bureau generally first defines a market(s), and then evaluates whether the allegedly dominant firm (or firms) substantially or completely controls that market, i.e., has a substantial degree of market power within that market. In this context, markets are defined in reference to both a product and geographic dimension, based on demand substitution in the absence of alleged anti-competitive conduct. The Bureau then considers evidence of the existence and magnitude of market power, such as market shares and barriers to entry.

iv. The second element considers the purpose of the impugned acts: whether the dominant firm (or firms) has engaged in a practice of conduct intended to have a predatory, exclusionary or disciplinary negative effect on a competitor. Exclusionary acts may make current or potential competitors less effective, for example by increasing their costs. Predatory acts involve a firm deliberately setting the price of a product(s) below an appropriate measure of its own cost to eliminate, discipline, or deter entry or expansion of a competitor. Disciplinary acts involve actions intended to dissuade an actual or potential competitor from competing vigorously, or otherwise disrupting the status quo in a market.

v. When evaluating the purpose of an act, the Bureau considers both subjective evidence of intent (for example, business documents describing the purpose of an act) as well as objective evidence in the form of the reasonably foreseeable consequences of an act. The Bureau will weigh any evidence of anti-competitive intent against evidence that the act was engaged in pursuant to a legitimate business justification, that is, evidence that indicates the purpose of the act was efficiency-enhancing or pro-competitive.

vi. The final element involves an analysis of whether competition – on prices, quality, innovation, or any other dimension of competition[2] – would be substantially greater in a market in the absence of the anti-competitive conduct. This assessment is a relative one, comparing the level of competition in a market with and without the alleged anti-competitive conduct, rather than an assessment of whether the absolute level of competition in a market is sufficient. The Bureau considers effects on both static competition (e.g., short-run prices and output), as well as dynamic competition (e.g., rivalry driven by product or process innovation).

vii. On application to the Tribunal, the Bureau must establish each element of section 79 on the balance of probabilities. To this end, when evaluating conduct under section 79, the Bureau considers whether clear, convincing, and cogent evidence exists in support of each element. The Bureau evaluates the body of evidence on the whole, and may consider the same evidence in reference to more than one element. As a result, the Bureau's analysis of different elements is often interconnected.

viii. Where all three elements of section 79 are present, the Tribunal may prohibit the person (or persons) who engaged in the conduct from continuing to do so. In addition, or alternatively, if the Tribunal concludes that a prohibition order is not likely to restore competition, it may make an order directing the person (or persons) who engaged in the conduct to take any action that is reasonable and necessary to overcome the anti-competitive effects of the practice, including the divestiture of assets or shares. Finally, if the Tribunal issues a remedial order, it may also order the respondent to pay an administrative monetary penalty of up to $10 million (or $15 million for each subsequent order) to promote practices by that person (or persons) that are in conformity with the purposes of section 79.

[2] To simplify the discussion, unless otherwise indicated, the term "price" in these guidelines refers to all dimensions of competition, such as quality or innovation. References to an increase in price encompass an increase in the monetary price, but may also refer to a reduction in quality, product choice, service, innovation or other dimensions of competition.

ix. When enforcing section 79, a significant consideration for the Bureau is to avoid chilling or deterring pro-competitive or efficiency-enhancing conduct. The Bureau recognizes that it is often challenging to distinguish anti-competitive conduct from aggressive competition on the merits, as in many cases the goal of aggressive competition is to marginalize rivals or eliminate them from a market. The Bureau recognizes that firms may acquire a dominant position by simply out-competing their rivals, for example, by offering higher quality products to consumers at a lower price. In these cases, sanctioning firms for simply being dominant would undermine incentives to innovate, outperform rivals and engage in vigorous competition. Such vigorous competition is the sort of competitive dynamic that the Act is designed to preserve and, where possible, enhance, as it ultimately leads to a more efficient allocation of resources.

x. In considering enforcement action under section 79 of the Act, the Bureau carefully evaluates allegations of abuse of dominance on a case-by-case basis, in the context of structural and other market-specific characteristics. In the course of an examination or inquiry, the Bureau will typically afford parties the opportunity to respond to the Bureau's concerns regarding alleged contraventions of section 79 and discuss an appropriate resolution to address them.

01 Dominance

1. Paragraph 79(1)(a) of the Act requires an assessment of whether "one or more persons substantially or completely control, throughout Canada or any area thereof, a class or species of business." In other words, this first element of the Act's abuse of dominance provision requires a finding of "dominance".

2. Four factors are relevant to assessing dominance: (i) a "class or species of business" – generally, a product market; (ii) "in Canada or any area thereof" – generally, a geographic market; (iii) "control" – a substantial degree of market power; and (iv) "one or more persons" – joint dominance.[3]

3. Market definition in abuse of dominance cases is an analytical tool that may assist with the determination of whether a firm is dominant.[4] The Tribunal has recognized that often it is neither possible nor necessary to precisely define a market (or markets) in proceedings under section 79.[5] In some cases, it may be clear that a firm is dominant under all plausible market definitions.

4. While the following discussion contemplates defining markets in the context of selling goods or services, a similar exercise can be conducted when defining input markets from the perspective of a dominant buyer.

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[3] For the remainder of this document the terms "firm", "person", and "entity" will be used interchangeably. Similarly, unless otherwise indicated, any reference to a single allegedly dominant person should be read to include reference to either a single dominant person or multiple dominant persons.

[4] As discussed further below, the Bureau may define different markets for the purposes of paragraphs 79(1)(a) and 79(1)(c). As such, market definition is also relevant to the assessment of competitive effects.

[5] TREB CT at para 132.

A. A "Class or Species of Business": Product Market

5. For the purposes of paragraph 79(1)(a), the Tribunal has held that a "class or species of business" is synonymous with a product market(s).[6]

6. Defining product markets usually begins by examining the product in respect of which the alleged abuse of dominance has occurred or is occurring, and determining whether close substitutes exist for that product, focusing on demand responses.[7]

7. The "hypothetical monopolist test" provides a useful framework to conceptualize substitutability between products – an analytical framework the Tribunal has recognized can be helpful in cases under section 79.[8] The Bureau considers whether a profit-maximizing hypothetical monopolist would impose and sustain a small but significant and non-transitory price increase for a candidate set of products above a given benchmark. In general, the smallest set of products in which the price increase would be sustained, including the product in respect of which the alleged abuse of dominance has occurred or is occurring, is defined as the product market.

8. Typically, the initial candidate market considered is a product in respect of which the alleged abuse of dominance has occurred or is occurring and its closest substitute. If a hypothetical monopolist could not impose a small but significant and non-transitory price increase above the benchmark, assuming the terms of sale of all other products remained constant, the candidate market is expanded to include the next-best substitute (which could include the products of other firms). The analysis is repeated until the point at which the hypothetical monopolist would profitably impose and sustain such a price increase over the candidate market.

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6 NutraSweet at 9. The term product also encompasses services (see subsection 2(1) of the Act).

7 The Bureau considers supply responses, or the ability of potential competitors to begin supplying in response to a price increase, when assessing the "control" element of paragraph 79(1)(a), such as when assessing market shares and participants, rather than when defining markets.

8 TREB CT at para 124.

9. For purposes of the hypothetical monopolist test, the Bureau generally considers a 5 percent price increase above the price level that would prevail absent the alleged anti-competitive act(s) to be significant and a one-year period to be non-transitory. Market characteristics may support using a different price increase or time period.

10. It is important to note that, in the context of abuse of dominance cases, the current price may not be the appropriate benchmark to use when defining the market, as some products that appear to be good substitutes at that price level might not be considered substitutes at price levels that would have prevailed in the absence of the alleged anti-competitive act(s).[9] Inclusion of these products could lead to an overly broad product market definition because these products do not discipline the market power of the dominant firm, but rather are only considered substitutes for products in the market at price levels where market power has already been exercised.

11. Direct evidence of buyer switching (i.e., changes in quantities purchased) in response to relative price changes can demonstrate substitutability for the purposes of market definition.[10] However, in practice, such direct evidence may be difficult to obtain.

12. For the above reasons, market definition for the purposes of section 79 will often focus on indicators of substitutability. Such indicators include:

- **Views, strategies, behaviours and identity of buyers**: Whether buyers have substituted between products in the past, and whether they plan to do so in the future, can indicate whether a price increase in a candidate market is sustainable. Industry surveys, industry participants and industry experts may also provide helpful information with respect to products that may be substitutable. Documents prepared by the firm in question in the ordinary course of business may also prove useful in this regard.

- **End-use and physical characteristics:** Functional interchangeability between two products is generally a necessary, but not sufficient, condition to warrant inclusion in the same market. In general, as buyers place greater value on the actual or perceived unique physical or technical characteristics of a product, the more likely it is that the product will fall within a distinct market.

9 TREB CT at paras 129-130.

10 When detailed data on the prices and quantities of the relevant products and their substitutes are available, statistical measures may be used to define product markets. Demand elasticities indicate how buyers change their consumption of a product in response to a change in the product's price (own-price elasticity) or in response to changes in the price of another identified product (cross-price elasticity). While cross-price elasticities do not directly measure the ability of a firm to increase price, they are particularly useful for determining whether differentiated products are close substitutes for one another.

- **Switching costs:** Transaction costs that buyers would have to incur to, among other things, retool, repackage, adapt their marketing, breach a supply contract or learn new procedures may render product substitution an unlikely response to a small but significant and non-transitory price increase.

- **Price relationships and relative price levels:** The presence of a strong correlation in price movement between two or more products over a significant period of time may suggest that the products fall within the same market.

13. The Bureau may consider it appropriate to define markets in reference to particular types of purchasers in certain circumstances, such as where sellers engage in price discrimination between different sets of buyers. For example, the Bureau may define two separate markets if a seller is able to effectively price discriminate between commercial customers and individual consumers. Similarly, the Bureau may define markets in reference to a particular level of a supply chain: for example, when assessing if a manufacturer is dominant in an industry where manufacturers sell through retailers, the Bureau may define a market as sales to retailers.

14. In some cases the Bureau may consider it appropriate to analyse several different (or potentially different) product markets together for the purposes of market definition. This could occur when evidence indicates that there may be more than one product market but that competitive conditions are sufficiently similar in each market such that analyzing them together does not affect the assessment of dominance. Where appropriate, the Bureau may analyse several geographic markets (discussed below) together in the same manner.

15. The Bureau may define a market as a group of diverse products that are not themselves substitutes for each other in cases where a sole, profit maximizing seller would increase the price of the group of the products because a sufficient number of buyers would not respond to the price increase by purchasing individual products from different sellers. This may occur, for example, where there are sufficiently large transaction costs associated with dealing with multiple sellers.

16. Special considerations arise when applying the hypothetical monopolist test to "multi-sided" platforms. For a multi-sided platform, demand for one "side" depends on use of another; one example would be an advertising service that matches buyers and sellers of a product, where greater buyer use increases the attractiveness to sellers, and greater seller use increases the attractiveness to buyers. Depending on the facts of a case, the Bureau may define a product market as one side of a multi-sided platform (i.e., consider the effects of a price increase on one side of the platform). However, when considering if a hypothetical monopolist would find it profit maximizing to impose that price increase, it may be necessary to account for the interdependence of demand, feedback effects, and changes in profit on all sides of the platform.[11] In other cases, the Bureau may view it appropriate to define a market to include multiple sides of the platform.

[11] See Visa at para 189. Similarly, where the Bureau has defined a market as one side of a platform the Bureau, where appropriate, may consider effects of conduct on multiple sides of the platform when evaluating issues beyond market definition.

17. Additionally, challenges may arise in the application of the hypothetical monopolist test where services are offered at a zero-monetary price (for instance, where services are offered for free to attract users to a multi-sided platform that depends on advertisers for monetization). In such cases, firms may compete on dimensions other than monetary price, such as product quality. Although the Bureau may seek to analyze whether a hypothetical monopolist would find it profit maximizing to decrease a relevant non-price dimension of competition by a small but significant amount for a non-transitory period of time, this may not be feasible in practise. As a result, the Bureau's analysis may focus on qualitative indicators of substitutability. This analysis will generally be similar to assessing substitutability based on qualitative indicators in other cases, as discussed above.

B. "Throughout Canada or any Area Thereof": Geographic Market

18. The Tribunal has held that the phrase "throughout Canada or any area thereof" is synonymous with a geographic market(s).[12]

19. A geographic market consists of all locations or supply points regarded as close substitutes by buyers. From a buyer perspective, a geographic market may include territory outside of Canada. Similar to product market definition, the Bureau will generally apply the hypothetical monopolist test to examine the dimensions of buyer switching, from suppliers in one location to suppliers in another, in response to a small but significant and non-transitory price increase. A geographic market will consist of all locations or supply points that would have to be included for such a price increase to be profitable. As with product market definition, the geographic parameters of the market may be overstated if they include areas that would not be included at the price level that would prevail absent the alleged anti-competitive act(s).

20. The Bureau may consider if the area in which the allegedly dominant firm operates constitutes a geographic market. However, the Bureau may ultimately define geographic markets more broadly or more narrowly. In the latter case, where an allegedly dominant firm operates in more than one geographic market, the Bureau will seek to assess if competitive conditions materially vary across those markets. If competitive conditions are similar in several geographic markets, the Bureau may consider them together for analytical purposes.

[12] NutraSweet at 20.

21. The Bureau will also consider indirect evidence of substitutability between locations or supply points when defining geographic markets, such as:

- **Views, strategies, behaviours and identity of buyers**: Considerations relating to convenience or the particular characteristics of the product (e.g., fragility, perishability) may influence a buyer's choice of supplier in the event of a price increase. The Bureau will examine past and potential future behaviour of buyers as new options are made available, through, for instance, advances in technology, which may impact the geographic dimension of a buyer's purchases. Third parties who are familiar with the industry in question may provide information regarding past and potential future industry developments that helps to define the geographic market. The extent to which distant supply locations are taken into account in business plans, marketing strategies and other documentation of the firm in question and of other sellers may also be useful indicators of geographic market definition.

- **Switching costs:** Transaction costs that buyers would have to incur to adapt their business to obtain the product from another source may render substitution to sources of supply from other geographic areas an unlikely response to a small but significant and non-transitory price increase.

- **Transportation costs, price levels, and shipment patterns:** In general, where prices in a distant area have historically exceeded or been lower than prices in the candidate geographic market by more than transportation costs, this may indicate that the distant area constitutes a separate market, for reasons that go beyond transportation costs. Conversely, if significant shipments of the product from a distant area in response to a price increase are likely, this may suggest that the distant area falls within the geographic market. In either case, the Bureau will assess whether a small but significant and non-transitory price increase in the candidate geographic market would change any locational pricing differential to the point where purchases from distant sellers may be able to constrain a price increase.

22. While the principles above apply equally to domestic and international sources of competition, other considerations, such as tariffs, duties, quotas, regulatory impediments, government procurement policies, intellectual property laws, exchange rate fluctuations and international product standardization may be relevant when considering whether supply points located outside Canada should be included in the geographic market.

C. "Substantially or completely control": Market Power

23. The Tribunal has held that the phrase "substantially or completely control" contemplates a substantial degree of market power.[13] The Supreme Court of Canada has defined "market power" as "the ability to 'profitably influence price, quality, variety, service, advertising, innovation or other dimensions of competition'";[14] the Tribunal has characterized a substantial degree of market power as one that "confers upon an entity considerable latitude to determine or influence price or non-price dimensions of competition in a market, including the terms upon which it or others carry on business in the market".[15] Market power may be reflected in an ability to restrict the output of other existing or potential market participants, and thereby profitably influence price (the "power to exclude").[16]

24. When assessing if a firm holds a substantial degree of market power, the Bureau considers the body of relevant information and/or documents on the whole in order to determine the extent to which a firm has the ability to influence the market. The exact nature of the Bureau's analysis and the weight accorded to any particular piece of information or document will depend on the circumstances of the case.

25. Market power can be measured directly or indirectly. Direct indicators of market power, such as evidence of supra-competitive profitability or pricing, are not always conclusive or indeed possible to assess; practical difficulties can arise in defining the "competitive" price level and the appropriate measure of cost to which prices should be compared.[17]

26. In many cases the Bureau examines a number of indirect indicators, both qualitative and quantitative, in conducting its analysis of market power, such as structural characteristics of a market (including market shares and any barriers to entry), the extent of technological change, the effects of a practice of anti-competitive acts, and customer or supplier countervailing power. The Bureau's analytical approach to the assessment of these indicators is discussed in greater detail below.

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13 TREB CT at para 173.

14 Tervita at para 44.

15 TREB CT at paras 174.

16 TREB CT at para 176.

17 The Tribunal has accepted some direct indicators as evidence of market power, such as a high price-to-average-cost margin and corresponding high accounting profits. Similarly, significant variations in price by region, along with the ability to lower prices in response to increased competition or entry, has been accepted by the Tribunal as evidence of supra-competitive pricing in higher-price regions. In these cases, direct indicators alone were insufficient to establish market power, which was substantiated through the use of indirect indicators. See Tele-Direct at 101 and Canada Pipe CT at para 161.

27. A firm that does not compete in a market may nonetheless substantially or completely control that market.[18] When assessing if a firm holds a substantial degree of market power in a market in which it does not compete the power to exclude current or potential competitors will often be the focus of the Bureau's analysis. Conversely, indicators of market power such as market shares or supra-competitive profits may not be relevant in such circumstances, whereas they may be central to assessing market power where the allegedly dominant firm does compete in the market.

28. In the context of paragraph 79(1)(a), the relevant level of market power includes not only a firm's pre-existing market power (i.e., any market power held by the firm notwithstanding any alleged anti-competitive conduct), but also market power derived from any alleged anti-competitive conduct.[19]

i. Market Shares and Barriers to Entry

29. Jurisprudence has often relied on a combination of high market shares and barriers to entry as evidence of market power. While there is no definitive numeric threshold, the Bureau is of the view that high market share is usually a necessary, but not sufficient, condition to establish the existence of a substantial degree of market power.[20]

30. All other things being equal, the larger the share of the market held by competitors, the less likely it is that the firm in question would be capable of exercising a substantial degree of market power. The ability of customers to switch to competitors if a firm attempts to increase price may be demonstrated by a large market presence of those competitors. In such cases, switching by a significant portion of a firm's customer base may be enough to render any increase in price unprofitable. However, the ability to switch may depend on various factors such as the speed and ease with which rival firms are able to accommodate increased demand for their products as the prices of rival suppliers increase, or any switching costs.

31. In addition to considering the market shares of current sellers of relevant products, the Bureau may also consider the shares of potential sellers that would participate in the market through a supply response if prices rose by a small but significant and non-transitory amount. In such a case, a firm could be considered a participant in the market if significant sunk investments are not required to enter, and it could rapidly and profitably divert existing sales or capacity to begin supplying the market in response to such a price increase. For those firms that would participate in the market through a supply response, market share calculations will include only the output or capacity that would likely become available to the market without incurring significant investment.

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18 TREB FCA 1 at para 13.

19 The Tribunal has held that the use of the present tense in paragraph 79(1)(a) means that at the time a person engages in a practice of anti-competitive acts, they must be in a position of dominance in the market (Direct Energy at para 40). The Bureau may conclude that paragraph 79(1)(a) is satisfied where a firm attains dominance through a practice of anti-competitive acts, provided that the firm is dominant at some point in time when the practice is ongoing.

20 However, as discussed in more detail below, in exceptional cases the Bureau may consider firms with relatively low market shares to possess a substantial degree of market power where other evidence establishes its existence.

32. Market shares can be measured in terms of revenues (dollar sales), demand units (unit sales), capacity (to produce or sell) or, in certain natural resource industries, reserves. If products in the market are homogeneous and firms are operating at capacity, relative market shares should be similar regardless of the unit of measurement. If firms have excess capacity, market shares based on capacity may best reflect their relative market position if they can easily increase supply in response to an increase in price. In the case of differentiated products, market shares based on dollar sales, demand units and/or capacity can lead to varying inferences with respect to firms' relative competitive positions, and shares based on revenues or demand units may be more probative in this regard. When calculating market shares, the Bureau will use the measurement that it considers best reflects the current and future competitive significance of competitors.

33. In contested abuse of dominance cases to date, market shares of those firms found to have abused their dominant position were very high, suggesting that, in those instances, customers were left with too few alternatives to discipline a price increase or other conduct by the firm that substantially lessened or prevented competition.[21]

34. In many cases, the Bureau uses market shares as an initial screening mechanism to assess allegations of abuse of dominance. The Bureau's general approach is as follows:

- A market share below 50 percent will generally only prompt further examination if other evidence indicates the firm possesses a substantial degree of market power, or that it appears the firm is likely to realize the ability to exercise a substantial degree of market power through the alleged anti-competitive conduct within a reasonable period of time while that conduct is ongoing;

- A market share of 50 percent 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 percent will generally prompt further examination.

35. In circumstances where the Bureau has not reached a final conclusion regarding the boundaries of the market, several plausible market definitions may present themselves. Where at least one plausible market definition exists that indicates an allegedly dominant firm possesses a substantial degree of market power, the Bureau may investigate further.

[21] In Tele-Direct, at 83, the Tribunal stated that it would require evidence of "extenuating circumstances, in general, ease of entry" to overcome a prima facie determination of control based on market shares of 80 percent and higher; whereas, in Laidlaw, the Tribunal observed that a market share of less than 50 percent would not give rise to a prima facie finding of dominance. However, this does not preclude the possibility that a substantial degree of market power could be found below that threshold.

36. The Bureau will also examine the durability of market shares in a particular market. If market shares have fluctuated significantly among competitors over time (for example, because firms regularly develop new technologies to "leapfrog" their competitors), a current high market share may be less indicative of a substantial degree of market power.

37. Market shares are not the only factor the Bureau considers, and where other evidence provides sufficient indication that a firm may be dominant regardless of a relatively low market share the Bureau may investigate further.[22] The types of evidence that may prompt the Bureau to investigate further include:

- **Direct evidence of market power:** Where available, evidence of supra-competitive pricing;
- **Significant Commercial Leverage:** Market or demand characteristics may provide the allegedly dominant firm sufficient commercial leverage over upstream or down-stream firms such that it may exercise a substantial degree of market power, for example, through the ability to affect a supplier's dealings with other customers;
- **Effects of the Anti-Competitive Acts:** An ability to cause prices to be higher in the market than would exist in the absence of the firm's conduct may be evidence of the existence and or/magnitude of market power on the part of that firm;[23] and
- **Other evidence of influence:** where a firm has otherwise demonstrated "considerable latitude"[24] to determine or influence a relevant dimension of competition.

38. The Bureau anticipates that, all else equal, these types of evidence are less likely to exist if the market share of the potentially dominant firm is small. However, there may be circumstances where market shares do not factor into the Bureau's analysis, for instance, where a firm controls a market through the ability to exclude, as discussed below.

39. A high market share is not itself sufficient to establish a substantial degree of market power. A firm's attempt to exercise market power may be thwarted by expansion or entry of existing and/or potential competitors on a sufficient scale and scope if expansion and/or entry are expected to be profitable. As a result, the Bureau considers the extent to which barriers to entry or expansion may

22 The Tribunal has recognized that firms with relatively low market shares may possess some degree of market power. For example, in the context of other provisions of Part VIII of the Act, the Tribunal has found a firm to possess market power with a share as low as 33 percent (**Visa** at para 267), and has recognized that market shares may either overstate or understate a firm's market power (Hillsdown at 318).

23 See, for instance, **TREB CT** at para 196.

24 See **TREB CT** at para 174.

limit the ability of rivals to respond to any exercise of market power. Barriers to entry or expansion can take many forms, including:

- **Sunk costs of entry or expansion:** Costs are sunk when they cannot be recovered if the firm exits a market. Sunk costs may pose a barrier to entry or expansion where the anticipated rewards to entry or expansion are anticipated to be less than the associated sunk costs, or there is sufficient risk that this will be the case as to have a deterrent effect;

- **Regulatory barriers:** In addition to their relevance to geographic market definition, regulatory controls relating to entry, tariff and non-tariff barriers to international or domestic trade may impede entry or expansion by competitors;

- **Economies of scale and scope:** Economies of scale occur when the average cost of producing a product declines the more of a product is produced, whereas economies of scope occur where the average costs of producing a product decline with the production of other products. Instances where such economies can be barriers to entry or expansion include when economies of scale prevent viable entry on a small scale or require entry to be on a sufficiently large scale to depress market prices, or where economies of scope require that a viable entrant must begin production of various products at once;

- **Market maturity:** Where market demand is not expected to increase, entry or expansion may be more difficult as any additional business must be converted from incumbents, rather than growth in market demand. Similarly, it may be easier to enter a market when it is young or growing, or less attractive to invest in assets that may be stranded due to decline in market demand;

- **Network effects:** Network effects occur when demand for a product depends on use of that product by others, and can be direct or indirect. Direct network effects occur when the demand for a product or service directly increases with more users, such as how the value of a communications network for an individual may increase with the number of other users of the network. In contrast, indirect network effects occur where greater use of a product or service by members of one group creates value for members of another group, potentially causing feedback effects. For example, in the case of a website that matches buyers and sellers of various products, the website becomes more valuable to buyers the more sellers use the website, and vice versa. All else equal a buyer may be indifferent to the number of other buyers that use the website, but if additional buyers attract additional sellers, a buyer indirectly benefits from greater use of the website by other buyers. Network effects may provide significant advantages to incumbent firms, making entry or expansion more difficult; and

- **Access to scarce or non-duplicable inputs:** An inability to access significant inputs that are required to be a viable competitor in a market may prevent entry or expansion.

40. The Bureau will examine the nature of any barriers to entry, including those created by the alleged practice of anti-competitive acts,[25] to assess whether entry would be timely, likely, and sufficient in scale and scope to make the exercise of a substantial degree of market power unsustainable. "Timely" means that entry will occur within a reasonable period of time; "likely" refers to the expectation that entry will occur; and "sufficient" means that entry would occur on a sufficient scale to prevent or deter firms from exercising a substantial degree of market power. When assessing if entry will satisfy these criteria, the Bureau will generally seek to determine if the threat of entry or expansion has an appreciable effect on the allegedly dominant firm's conduct.

ii. The Ability to Exclude

41. As noted above, the Tribunal has recognized that the ability to exclude – the ability to restrict the output of other actual or potential market participants, and thereby profitably influence price – constitutes market power.[26] Where through the impugned conduct assessed under paragraphs 79(1)(b) and 79(1)(c) a firm has demonstrated its ability to exclude rivals, this provides evidence that it has market power.[27]

42. Assessing the existence and degree of market power through the ability to exclude is particularly relevant when a firm does not compete in a market in which the alleged anti-competitive effects are alleged to be occurring. A firm that does not compete in a particular market may nonetheless control it, for example, through control of a significant input to competitors in a market, or the ability to make rules that effectively control the business conduct of those competitors.[28] The Bureau does not view these two mechanisms as mutually exclusive: for example, a firm may leverage control of a significant input in order to impose and enforce rules that affect the business conduct of competitors in a market.

43. When assessing whether a firm controls a significant input in a market in which it does not compete (e.g., a downstream market), the Tribunal has indicated it is not necessary to define and establish dominance in an additional market defined around that input (e.g., an upstream market).[29] However, for the purposes of assessing if control of that input provides the ability to exclude, the Bureau will consider the extent to which substitutes exist to the input provided by the allegedly dominant firm, as well as the extent to which that input is necessary to compete. In the absence of

25 Laidlaw at 331; Tele-Direct, at 95; Canada Pipe CT at paras 138, 146; Canada Pipe FCA 2 at paras 24-25, 36.

26 TREB CT at para 176.

27 TREB CT at paras 182, 190, 254(n).

28 TREB FCA 1 at para 13.

29 TREB CT at paras 203-207.

acceptable substitutes, and if competitors in the market are unable to effectively compete without access to the input, the Bureau will conclude the allegedly dominant firm has a substantial degree of market power in that market (in the examples above, in the downstream market).

44. When assessing if a firm has the ability to impose rules that govern the conduct of competitors, the Bureau may consider the extent to which any rules are adhered to, or could be enforced by the allegedly dominant firm. If such rules are not adhered to or enforced, the Bureau is not likely to conclude the allegedly dominant firm has a substantial degree of market power on that basis.

iii. Other Factors

45. The Bureau may examine other potentially relevant indicators when assessing the existence and/or magnitude of market power, including:

- **Countervailing power:** A customer or supplier may have the ability and incentive to constrain a firm's attempt to exercise a substantial degree of market power, such as by vertically integrating its own operations; refusing to buy or sell other products or in other geographic markets from the firm; or encouraging expansion or entry of existing or potential competitors; and

- **Technological change and innovation:** Evidence of a rapid pace of technological change and the prospect of firms being able to "innovate around" or "leapfrog" an apparently entrenched position of an incumbent firm could be an important consideration, along with change and innovation in relation to distribution, service, sales, marketing, packaging, buyer tastes, purchase patterns, firm structure and the regulatory environment.

D. "One or more persons": Joint Dominance

46. Section 79 contemplates that a group of firms may jointly substantially or completely control a market, satisfying paragraph 79(1)(a). The Bureau's analytical framework for assessing joint dominance is similar to that employed in examining single-firm dominance, and likewise focusses on the existence of a substantial degree of market power. Similar to single-firm dominance, the Bureau considers the ability of a firm or firms to exercise a substantial degree of market power, taking into account market shares, barriers to entry and expansion and any other relevant factors. However, in the case of joint dominance, this exercise also requires an assessment of whether those firms that are alleged to be engaged in a practice of anti-competitive acts jointly control a class or species of business such that they hold a substantial degree of market power together.

47. As with single-firm dominance, the Bureau will assess the extent to which competition from existing rivals and from potential rivals (i.e., entrants) outside the allegedly jointly dominant group is likely to defeat the profitability of a price increase by the firms that are alleged to be jointly dominant. If these two sources of competition are not likely to constrain a price increase, the Bureau will then consider the nature of competition within the allegedly jointly dominant group.

48. In the absence of a sufficient competitive constraint from outside an allegedly jointly dominant group, if competition among group members is also insufficient to constrain prices to the competitive level, members of that group will be able to jointly exercise a substantial degree of market power. As a result, when assessing joint dominance, the Bureau may accord significant weight to how vigorously the allegedly jointly dominant firms compete with each other.[30] In the absence of vigorous competition the Bureau may conclude that the lack of mutual competitive constraint permits them to exercise a substantial degree of market power.

49. Similar or parallel conduct by firms is insufficient, on its own, for the Bureau to consider those firms to hold a jointly dominant position. Further, evidence of coordinated behaviour by firms in the allegedly jointly dominant group may be probative insofar as it may explain why members of the allegedly dominant group are not vigorously competing. However, the Bureau does not consider such evidence as necessary to establish that a group is jointly dominant, if there is other evidence that competition among members of the allegedly dominant group is not sufficient to discipline their exercise of a substantial degree of market power.

50. As with single-firm dominance, the ability to exercise a substantial degree of market power on a collective basis is not in and of itself sufficient to raise an issue under the abuse provisions of the Act. While a group of firms may collectively be able to exercise a substantial degree of market power, it is still necessary to establish that these firms' conduct constitutes a practice of anti-competitive acts that is preventing or lessening competition substantially. It may, however, be the case that a practice of anti-competitive acts facilitates joint dominance. For example, joint dominance may be enabled or reinforced through disciplinary conduct, as discussed below.

30 Prices that appear to be at or near the competitive level could be evidence of vigorous competition. Other factors may include, but are not limited to, price competition among competitors, instability of market shares over time, attempts to solicit rival's customers, or "leapfrog" competition through innovation. Conversely, the absence of these factors on the part of firms within the allegedly jointly dominant group could indicate that these firms are not competing vigorously with one another.

02 Anti-competitive Acts

51. Paragraph 79(1)(b) requires that a firm or firms "have engaged in or are engaging in a practice of anti-competitive acts". This element consists of two factors, the Bureau's approach to which is discussed below: (i) a "practice"; and (ii) anti-competitive acts.

A. A "Practice"

52. While a "practice" normally involves more than one isolated act, the Bureau considers that this element may be satisfied by a single act that is sustained and systemic, or that has had or is having a lasting impact in a market.[31] For example, a long-term exclusionary contract may effectively prevent the entry or expansion of competitors despite the fact that the contract itself could be viewed as a single act.

B. Anti-competitive Acts

53. Section 78 of the Act enumerates a non-exhaustive list of acts that are deemed to be anti-competitive in applying section 79.[32] An anti-competitive act is defined by reference to its purpose, and the requisite anti-competitive purpose is an intended negative effect on a competitor that is predatory, exclusionary, or disciplinary.[33] While many types of anti-competitive conduct may be intended to harm competitors, the Bureau considers that certain acts not specifically directed at competitors could still be considered to have a predatory, exclusionary, disciplinary, or some other

31 Canada Pipe FCA 1 at para 60.

32 In addition, subsection 79(5) states that "For the purpose of this section, an act engaged in pursuant only to the exercise of any right or enjoyment of any interest derived under the *Copyright Act, Industrial Design Act, Integrated Circuit Topography Act, Patent Act, Trade-marks Act* or any other Act of Parliament pertaining to intellectual or industrial property is not an anti-competitive act." For information on the Bureau's approach to reviewing business conduct involving intellectual property, see the Bureau's ***Intellectual Property Enforcement Guidelines.***

33 Canada Pipe FCA 1 at para 66.

anti-competitive purpose.[34] On the latter, by way of example, conduct aimed at undermining the competitive process and the vigour with which other firms may compete may be considered as having the requisite anti-competitive purpose.

54. When assessing whether an act is anti-competitive, the purpose of an act may be established directly by evidence of subjective intent, inferred from the reasonably foreseeable consequences of the conduct, or both. Although verbal or written statements of a firm's personnel may assist in establishing subjective intent, evidence of subjective intent is neither strictly necessary nor completely determinative.[35] In most cases, the purpose of the act can be inferred from the circumstances, and persons are assumed to intend the reasonably foreseeable consequences of their acts.[36]

55. In some cases, when evaluating the overall character of a practice, evidence that the conduct was motivated by a legitimate business justification can outweigh evidence of anti-competitive purpose when the two are balanced against each other. The role of business justifications in evaluating the purpose of conduct is discussed further below.

56. For the purposes of paragraph 79(1)(b), a competitor is a person who competes in a market, and need not be a competitor of the allegedly dominant firm.[37] Thus, a firm that does not compete in a market may nonetheless engage in a practice of anti-competitive acts directed toward competitors in that market.

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34 The Federal Court of Appeal and Tribunal have acknowledged that paragraph 78(1)(f) does not contain an explicit reference to a purpose vis-à-vis a competitor. The Federal Court of Appeal has characterized the conduct in paragraph 78(1)(f) as reflecting "a self-serving intent, not a relative one intended to harm a competitor", and that on the premise of its earlier jurisprudence "requiring a predatory, exclusionary, or disciplinary negative effect on a competitor in all cases would render paragraph 78(1)(f) meaningless" (TREB FCA 2 at para 54).

35 Canada Pipe FCA 1 at paras 72-73.

36 NutraSweet at 35.

37 TREB CT at para 277; TREB FCA 1 at paras 17-20.

57. Where a firm that does not compete in a market is alleged to have engaged in a practice of anti-competitive acts, the Tribunal has indicated that it must be satisfied that the firm has a "plausible competitive interest" in adversely impacting competition in that market.[38] As noted above, the Federal Court of Appeal has characterized anti-competitive acts as those that have an intended negative effect on a competitor that is predatory, exclusionary, or disciplinary. Although the Bureau will typically consider the incentives of a dominant firm to limit competition, the Bureau may conclude that a firm that does not compete in a market has engaged in a practice of anti-competitive acts where an exclusionary, predatory, disciplinary, or other anti-competitive purpose can be demonstrated.

58. In assessing whether a particular act is likely to be anti-competitive, the Bureau is of the view that anti-competitive conduct generally falls into three broad categories: (i) predatory conduct; (ii) exclusionary conduct; and (iii) disciplinary conduct.

i. Predatory Conduct

59. Predatory conduct involves a firm deliberately setting the price of a product(s) below an appropriate measure of its own cost to incur losses on the sale of product(s) in the market(s) for a period of time sufficient to eliminate, discipline, or deter entry or expansion of a competitor, in the expectation that the firm will thereafter recoup its losses by charging higher prices than would have prevailed in the absence of the impugned conduct.[39] Predatory pricing may be implicit (through discounts or rebates, for example), or explicit.

60. The Bureau considers that average avoidable cost is the most appropriate cost standard to use when determining if a dominant firm's prices are below cost.[40] Avoidable costs refer to all costs that could have been avoided by a firm had it chosen not to sell the product(s) in question. Whether a cost is avoidable depends in part on the duration of the alleged predation as, in general, more costs become avoidable over time. Where the firm's pricing of the product(s) does not cover its own average avoidable costs, the Bureau will consider the pricing to be predatory in the absence of evidence that the overriding purpose of the conduct was in furtherance of a credible efficiency or pro-competitive rationale. For example, it may be reasonable for a firm to sell excess, obsolete or perishable products at below-cost prices. Similarly, companies may use below-cost promotional pricing to induce customers to try a new product.

38 **TREB CT** at paras 279-282.

39 The Bureau will typically consider the question of whether a firm can recoup any losses incurred in predation in the analysis of whether the conduct has given rise to a substantial lessening or prevention of competition pursuant to paragraph 79(1)(c). In many cases the ability to recoup losses from predation will depend on barriers to entry that prevent new entry in response to supra-competitive prices, or re-entry by predated firms. In the absence of recoupment in the past, present, or likely recoupment in the future, the Bureau would not typically consider paragraph 79(1)(c) to be satisfied.

40 **Air Canada** at paras 76, 80.

61. There are difficulties inherent in applying a price-cost test to identify predatory pricing, all other things being equal. The Bureau generally uses various "screens" prior to conducting an avoidable cost analysis. Specifically, the Bureau will examine whether the alleged predatory price can be matched by competitors without incurring losses (suggesting that discipline or exclusion, and subsequent recoupment, is unlikely to occur), as well as whether the alleged predatory price is in fact merely meeting competition by reacting to match a competitor's price.

ii. Exclusionary Conduct

62. In general, the Bureau is not concerned with conduct that forces competitors to be more effective, but rather with conduct that makes it more difficult for competitors to be effective. Vigorous competition on the merits (e.g., offering superior services at a lower price) may force competitors to be more effective or result in their exit from a market, but does not engage the abuse of dominance provisions. In contrast, exclusionary conduct is designed to make current and/or potential rivals less effective, to prevent them from entering the market, or to eliminate them from the market entirely. Such conduct often does so by raising rivals' costs or reducing rival's revenues.

63. In a non-exhaustive list, section 78 describes various means by which a firm may engage in exclusionary conduct. These include: margin squeezing of a downstream competitor by a vertically-integrated supplier; vertical acquisitions; pre-empting scarce facilities or resources; adopting incompatible product specifications; and exclusive dealing. Other exclusionary strategies can include tying and bundling, and conduct that increases customer switching costs. All such activities can, in certain circumstances, serve to increase a rival's costs and/or reduce their revenues, which may make it more difficult for the rival to compete or result in its exclusion from the market.

64. The following is a brief discussion of three types of exclusionary conduct that may raise issues under the abuse of dominance provisions: exclusive dealing, tying and bundling, and refusals to supply. These are not the only categories of exclusionary conduct, nor are they mutually exclusive. Indeed, in the Bureau's experience, individual anti-competitive acts may be viewed as part of more than one category, or otherwise blur the lines between them. For instance, the implementation of a tie can have the effect of inducing a firm's customers to exclusively purchase a tied product from that firm.

Exclusive Dealing

65. Exclusive dealing occurs when a firm supplies its product or products to a customer on the condition that the customer or supplier buy and/or sell only those versions of the product(s). In addition or alternatively, exclusive dealing may also occur when a firm requires that customers (or suppliers) do not buy (and/or sell) products of competitors. Exclusive dealing can also take the form of a firm requiring or inducing its own suppliers to deal only with the firm itself and not with that firm's competitors. Exclusivity may be mandated explicitly, or induced through other methods, such as technological incompatibilities, requirements contracts, meet-or-release clauses, most-favoured-nation (MFN) clauses, or other contractual practices.

66. Exclusive dealing is not necessarily anti-competitive, and is often engaged in for reasons other than to exclude competitors. For example, exclusive dealing may solve "free rider" problems where a firm supplying a product to a downstream retailer also provides some service component, technological information, or aftermarket support that improves the product for consumers. If the retailer can use this information to improve the products of rival suppliers as well, the firm, without contractual protection, will have little incentive to provide this support. In such a case, exclusive dealing may preserve such an incentive to offer these services, which is generally to the benefit of consumers.

67. However, by inducing exclusivity from a sufficient quantity of suppliers or customers, a dominant firm may raise barriers to entry or expansion by raising rivals costs. Examples of how this may be achieved include denying rivals sufficient business to achieve economies of scale, preventing rivals from accessing necessary inputs, forcing rivals to compensate customers for the penalties incurred for switching, or inducing rivals to inefficiently vertically integrate.

Tying and Bundling

68. Tying occurs when, as a condition of obtaining or using one product (the "tying" product), a firm requires or induces a customer to purchase another product as well (the "tied" product). Closely related, bundling typically refers to situations whereby products are sold together in fixed proportions. Tying and bundling are ubiquitous in many industries, as many items for sale can be viewed as distinct tied products or a bundle of different components. In many cases there are often strong cost efficiencies that motivate tying and bundling.

69. However, to the extent a tying or bundling strategy excludes, predates, or disciplines a competitor it may raise concerns under the abuse of dominance provisions of the Act. In particular, the Bureau will consider whether the tie excludes competitors in whole or in part by increasing their costs or reducing their revenue. For instance, a tie may result in a firm with a substantial degree of market power in one market creating, enhancing or maintaining its market power in a second market. Like exclusive dealing, tying may increase switching costs for consumers, deny rivals economies of scale or scope necessary for efficient production, or induce inefficient production choices by rivals.

70. Before concluding that a firm is engaging in tying, the Bureau will seek to determine whether the alleged tying and tied products are in fact separate products. A central question in the inquiry is the extent to which separate customer demand exists for the tying and tied products. The Bureau may also consider efficiencies that arise from a tie; if, for example, implementing a tie gives rise to efficiencies such that it is not commercially viable to offer the products separately, the Bureau would not conclude the tying and tied products to be separate products notwithstanding consumer demand.

Refusals to Supply

71. As a general matter, there is no obligation on any business to supply to, or buy a product from, another business. However, in some exceptional circumstances, refusals to supply may engage the abuse of dominance provisions.

72. In some cases, a firm may explicitly refuse to supply a product. However, concerns may also arise in relation to "constructive" refusals, where a firm agrees to supply on terms that are sufficiently onerous as to have the same effect as an explicit denial (e.g., charging a prohibitively high price).

73. For the Bureau to conclude that a refusal to supply is an anti-competitive act, it must be the case that the product or service being denied is both competitively significant and cannot otherwise be feasibly obtained (for example, from other suppliers or through self-supply). Where this is the case, the Bureau may conclude that it was reasonably foreseeable that the purpose of a refusal was to exclude a competitor, in the absence of a legitimate business justification.

74. When exercising its enforcement discretion in relation to refusals to supply, the Bureau is aware that competitively significant inputs are often the result of significant and costly investment and innovation, and forcing firms to supply may undermine incentives for firms to develop new and beneficial products and services.

iii. Disciplinary Conduct

75. The Bureau considers that a dominant firm engages in disciplinary conduct where it undertakes actions intended to dissuade an actual or potential competitor from competing more vigorously, or otherwise disrupting the status quo in a market. Such conduct may not have a predatory or exclusionary purpose, but rather, be intended to soften competition. Section 78 provides two examples of potentially disciplinary conduct: paragraph 78(1)(d) contemplates the use of fighting brands to discipline a competitor, and paragraph 78(1)(i) refers to discipline through selling articles at a price lower than their acquisition cost.

76. Disciplinary conduct may play a role in facilitating, maintaining, or inducing coordination among firms. In many cases when firms engage in coordinated conduct, each participant faces an incentive to deviate from the coordinated outcome. For example, where firms coordinate in order to raise prices in a market, each participant in the coordination may have the incentive to lower its own prices in order to win additional sales from the other participants at the elevated prices. As a result, one of the requirements for coordinated behaviour to likely be sustainable is the ability to respond to any deviations from the terms of coordination through credible deterrent mechanisms. Disciplinary conduct may provide such a mechanism: by engaging in disciplinary conduct, a dominant firm can induce or preserve coordination by punishing – or credibly threatening to punish – deviations from a coordinated outcome.

77. Disciplinary conduct may also include actions that do not directly punish rivals, but rather, facilitate punishments or increase the credibility of threats to punish rivals. For example, if a firm adopts contractual terms with its customers that provide the firm with more information about the extent to which rivals are deviating from supra-competitive pricing, thereby increasing the likelihood discipline will occur, the Bureau may consider the contractual terms to be disciplinary conduct.

78. In assessing whether the purpose of a practice is disciplinary, the Bureau may be more likely to rely on subjective evidence of intent than when assessing other types of anti-competitive acts, particularly where the alleged disciplinary conduct consists of pricing behaviour alone. Because such disciplinary acts may be particularly difficult to distinguish from vigorous competition on the merits, the Bureau may be hesitant to conclude that an act has a disciplinary purpose based solely on its reasonably foreseeable consequences.[41] When evaluating evidence of subjective intent, the Bureau will typically look for evidence of "something more" than the typical intent of a firm to best its competition. For example, where evidence indicates that a firm engaged in an aggressive competitive response not to meet (or beat) competition from a rival, but instead to induce that rival to compete less vigorously, the Bureau may conclude that "something more" is present.

79. Given the above, the Bureau anticipates that it would investigate allegedly disciplinary conduct in limited circumstances, and that it would generally have to be satisfied that the alleged conduct is disciplinary on its face.[42]

41 Exceptions to this approach may exist. For example, if a firm engaged in similar behaviour after being sanctioned for disciplinary conduct, or if the Bureau observed substantially similar conduct in a market in which disciplinary conduct had previously taken place, the Bureau may put less of a focus on subjective evidence of intent.

42 The Bureau recognizes that difficulties may arise identifying an appropriate remedy for disciplinary anti-competitive acts. As with other conduct actionable under section 79, the appropriate remedy for a disciplinary act will ultimately depend on the specific facts of any given case. When determining the appropriate remedy for disciplinary conduct the Bureau will have regard to the spectrum of options afforded by section 79, including administrative monetary penalties where appropriate.

iv. Business Justifications

80. An additional factor in the determination of whether an act is anti-competitive is whether it was in furtherance of a legitimate business objective. A business justification is not a defence to an allegation that a firm has engaged in anti-competitive conduct, but rather, an alternative explanation for the overriding purpose of that conduct. Proof of the existence of **some** legitimate business purpose underlying the conduct is not sufficient. Rather, the Federal Court of Appeal has said that "a business justification must be a credible efficiency or pro-competitive rationale for the conduct in question, attributable to the respondent, which relates to and counterbalances the anti-competitive effects and/or subjective intent of the acts."[43] Depending on the circumstances, this could include, for example, reducing the firm's costs of production or operation, or improvements in technology or production processes that result in innovative new products or improvements in product quality or service.[44] Compliance with a statutory or regulatory requirement may also constitute a business justification, where an act is required to comply with that statutory or regulatory requirement.[45]

81. Although the Bureau will consider any business justifications posited by the allegedly dominant firm, as the courts have recognized, where an allegedly dominant firm asserts a business justification it ultimately bears the burden of proof to establish it.[46]

82. In assessing the overriding purpose of an alleged anti-competitive act, the Bureau will examine the credibility of any efficiency or pro-competitive claims raised by the allegedly dominant firm, their link to the alleged anti-competitive act, and the likelihood of these claims being achieved. In this assessment, the Bureau may seek evidence as to the role the asserted efficiency or pro-competitive justification played in the allegedly dominant firm's decision-making. In the absence of contemporaneous evidence that the asserted business justification rationally motivated the allegedly dominant firm, the Bureau will be less likely to conclude that the business justification is credible.

43 Canada Pipe FCA 1 at para 73.

44 However, as the Tribunal has recognized, it is necessary to consider all known circumstances; for example, cost reductions that may be contemplated or realized by driving one's rivals from a market would not suffice to shield conduct that was primarily motivated by a predatory, exclusionary or disciplinary purpose (see TREB CT at para 295).

45 TREB FCA 2 at para 146.

46 TREB FCA 2 at para 144.

83. Additionally, after finding evidence in support of both an anti-competitive purpose and a claimed business justification, when assessing the overall character of a practice the Bureau may consider whether the claimed efficiency or pro-competitive benefits could have been achieved by credible alternate means that would have had a lesser impact on competitors, where appropriate. In conducting this analysis the Bureau would typically only consider alternative methods to achieve a business objective where either subjective evidence establishes the allegedly dominant firm considered those alternatives or there is clear objective evidence that it would be unreasonable for that firm to not have considered those alternatives (e.g., if a firm changes the manner in which it pursues a business objective, the Bureau would generally presume the firm considered maintaining its previous course of action).

84. Consistent with an approach noted by the Tribunal, when assessing the overall character of a practice the Bureau may consider if the alleged anti-competitive acts made no economic sense but for their anti-competitive effect on a competitor.[47] Conduct that makes no reasonably foreseeable economic sense but for an anti-competitive effect is likely to have an overarching anti-competitive purpose. However, circumstances may arise where the Bureau finds a practice satisfies paragraph 79(1)(b) even when, evaluating its reasonably foreseeable consequences, it may make economic sense without an anti-competitive effect on a competitor. Such cases may include where evidence of subjective intent establishes an anti-competitive purpose, or where the reasonably foreseeable economic benefits resulting from exclusion are sufficiently large compared to the other profits derived from the practice to make it clear that the overarching purpose was an anti-competitive effect on a competitor.[48]

47 TREB CT at paras 311-318. In addition, the Tribunal indicated that it may also have regard to whether the acts involved the sacrifice of short-term profits that would not be recouped but for the exclusion of a competitor. The Bureau's approach to such analysis is similar to what is set out above with respect to the no economic sense analysis.

48 When analyzing whether conduct made no reasonably foreseeable economic sense but for the exclusion of a competitor, the Bureau will not always consider the appropriate counterfactual scenario (against which to assess relative economic benefits) to be the one in which the firm took no action whatsoever. For instance, where a firm is presented with two options and elects to pursue the one in which it foresees deriving greater profits due to exclusion (and lower profits from other sources) than the alternative, the Bureau would consider this to make no economic sense but for the exclusion of a competitor.

85. Business justifications are relevant to the assessment of anti-competitive purpose and do not directly bear on the analysis of competitive effects pursuant to paragraph 79(1)(c).[49] The Bureau is not required to quantify any efficiencies resulting from a practice of anti-competitive acts, but will consider any such efficiencies within the purpose-focussed assessment of paragraph 79(1)(b).[50]

49 Canada Pipe FCA 1 at para 87.

50 The Tribunal has recognized that business justifications "do not give rise to the quantitative assessment contemplated by the efficiency exception in section 96 of the Act" and that "it would be much more difficult, and perhaps even completely intractable, in the section 79 context" (TREB CT at para 291).

03 Competitive Effects

86. Paragraph 79(1)(c) requires that the conduct in question "has had, is having or is likely to have the effect of preventing or lessening competition substantially in a market". In other words, having determined that the firm is dominant and has engaged in a practice of anti-competitive acts, it remains necessary to determine whether this practice has resulted or is likely to result in substantial harm to competition in one or more markets.[51] Generally speaking, a substantial lessening or prevention of competition occurs when an impugned practice causes a materially greater degree of market power to exist than in the absence of the practice.

87. Demonstrating a substantial lessening or prevention of competition does not entail an assessment of whether the absolute level of competition in a market is substantial or sufficient, but is instead a relative assessment of the level of competitiveness in the presence and absence of the impugned practice. In carrying out this assessment, the Bureau's general approach is to ask whether, but for the practice in question, there would likely be substantially greater competition in the market in the past, present, or future.[52]

88. To satisfy paragraph 79(1)(c), conduct can either **lessen** or **prevent** competition. The Tribunal has recognized that the general analytical approach is similar in either case, but important differences exist. Conduct that lessens competition typically permits the exercise of new or increased market power through lessening the constraint posed by current or potential competitors. Conduct that prevents competition, in contrast, typically preserves existing market power by preventing new competition that would have materialized in the absence of the impugned practice.[53]

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51 When assessing competitive effects pursuant to paragraph 79(1)(c) the Bureau analyzes effects in reference to a market, which in turn engages the concepts of market definition. The Bureau is of the view that the markets for the purposes of paragraphs 79(1)(a) and 79(1)(c) need not be the same; that is, section 79 may apply where a firm is dominant in one market but substantially lessens or prevents competition in another (see, for instance, Tele-direct at 214). When necessary, the Bureau applies the same approach to market definition for the purposes of paragraph 79(1)(c) as it does in reference to paragraph 79(1)(a), discussed above.

52 This test was accepted by the Federal Court of Appeal in Canada Pipe FCA 1 at para 38. The Court stated that other tests might also be appropriate depending on the circumstances.

53 TREB CT at paras 472-474.

89. In many cases, a substantial lessening or prevention of competition is accomplished by erecting or strengthening barriers to entry or expansion. Through increased barriers to entry or expansion, competitors or potential competitors are inhibited or deterred from competing as vigorously as they otherwise would, thereby disciplining the exercise of market power.[54] In examining anti-competitive acts and their effects on barriers to entry or expansion, the Bureau focuses its analysis on determining the state of competition in the market in the absence of these acts. If, for example, it can be demonstrated that, but for the anti-competitive acts, an effective competitor or group of competitors would likely emerge within a reasonable period of time to challenge the exercise of market power, the Bureau will conclude that the acts in question result in a substantial lessening or prevention of competition.[55]

90. Although the Bureau's conceptual approach focusses on increased barriers to entry or expansion, the Bureau may also assess the effects of a practice of anti-competitive acts on various indicators of the intensity of competition. Such indicators include whether, in the absence of the practice of anti-competitive acts, the extent to which:

- monetary prices would be lower;
- product quality, service, innovation, or choice would be greater; or
- switching between products or suppliers would be more frequent.

54 This could include causing rivals to adopt more accommodating competitive reactions.

55 When assessing a reasonable time period for potential competitors to provide effective competition in the absence of the anti-competitive acts, the Bureau will assess the time required for competitors to develop products and marketing plans, to build facilities or make adjustments to existing facilities, and to achieve a level of sales sufficient to prevent or discipline a material price increase by dominant firms. The Federal Court of Appeal has held that a duration of two years will usually be sufficient to establish an effect (TREB FCA 2 at para 64).

91. Whether any lessening or prevention of competition is substantial is assessed in terms of its degree, duration, and the extent to which it extends throughout the market. There is no definitive threshold past which a given lessening or prevention qualifies as substantial. Rather, substantiality is assessed based on market specific factors, including the market power of the allegedly dominant firm. As the Tribunal has confirmed, "where a firm with a high degree of market power is found to have engaged in anti-competitive conduct, smaller impacts on competition resulting from that conduct will meet the test of being "substantial" than where the market situation was less uncompetitive to begin with." [56]

92. When assessing whether a practice of anti-competitive acts gives rise to a substantial lessening or prevention of competition, the Bureau may rely on either qualitative (e.g., business documents, views of industry participants, etc.) or quantitative evidence (e.g., econometric studies).[57] The Bureau seeks to evaluate the causal impact of the practice of anti-competitive acts by comparing the state of competition in the market to a counter-factual scenario where the practice did not take place. In conducting this assessment, the Bureau may seek evidence that directly speaks to the counter-factual scenario (e.g., the views of market participants), as well as evidence from natural experiments in the market at issue or in other markets.

93. Natural experiments are often useful to assess a counterfactual by examining historical events that link changes in competitive conditions (e.g., entry or exit of firms, presence of certain competitors, products, services, or contractual practices) to changes in observable effects. In appropriate circumstances, the study of events and their impact on competition in one market can be very informative to an assessment of likely effects in another market. For example, the Bureau may seek evidence on how competitive outcomes differ in similar markets where the impugned conduct did not take place, or examine evidence relating to the state of competition in the market before and after a practice of anti-competitive acts (or other events, such as the exit of a competitor) to determine its causal effect.

94. When assessing the impact of a practice of anti-competitive acts, the Bureau may consider effects on both static competition (e.g., the impact on prices and output) and dynamic competition (e.g., rivalry driven by product or process innovation). Indeed, conduct that creates or enhances barriers that reduce dynamic competition, such as innovation, which the Tribunal has characterized as "the most important form of competition",[58] is of particular concern to the Bureau. However, due to its forward-looking and uncertain nature, effects on dynamic competition are often more challenging to assess than effects on static competition. In such cases, natural experiments from other markets (where available) may assist in establishing competitive effects.

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56 Tele-Direct at 247.

57 Although in certain circumstances the Bureau may undertake quantitative studies of competitive effects when assessing potential abuses of dominance, it is not necessary for the Bureau to adduce quantitative evidence to establish a substantial prevention or lessening of competition (**TREB FCA 2** at paras 101, 104).

58 **TREB CT** at para 712.

95. The potential for enforcement action to chill dynamic competition in favour of increased static competition is an important consideration for the Bureau in determining whether to pursue an enforcement action, or even what remedy to pursue if enforcement action is warranted. Healthy dynamic competition may result in sequential "winner take all" competition for a market based on product quality or innovation, with the result that the successful firm acquires market power. Often, it is the prospect of market power that provides the incentive for firms to engage in dynamic competition. Focussing enforcement on static outcomes may result in longer term harm as it may undermine the incentives for firms to engage in beneficial dynamic competition, and caution must be exercised when intervening in fast-moving markets. However, this potential result does not give dominant firms a license to lessen or prevent competition. In particular, where a dominant firm raises barriers that prevent more (or potentially more) innovative rivals from challenging its position, the Bureau will not hesitate to take action where appropriate.

04 Remedies

96. The Bureau considers potential remedies early in any investigation or inquiry under section 79 in order to determine the nature, scope, and the means by which a remedy may be implemented. Where the Bureau is satisfied that the evidence supports a conclusion that section 79 is engaged, a number of avenues to remedy the situation are available.

A. Consensual Resolutions

97. Generally speaking, in using the range of enforcement tools available, the Bureau encourages and facilitates voluntary compliance and will often attempt to achieve a negotiated settlement in response to a breach of section 79.[59]

98. Where the Bureau has concluded section 79 is engaged, in most circumstances the Bureau will require that any proposed remedy agreed upon be formalized in a consent agreement and registered with the Tribunal pursuant to section 105 of the Act.[60] Consent agreements entered into by the Bureau and a respondent must be based on terms that could be the subject of an order of the Tribunal. Upon registration, consent agreements have the same force and effect as orders of the Tribunal.

[59] See also the Bureau's ***Competition and Compliance Framework***.

[60] Where the Commissioner has concluded the elements of section 79 are satisfied, the Commissioner will not typically discontinue an inquiry or application if the dominant firm unilaterally ceases its practice of anti-competitive acts unless the dominant firm enters into a consent agreement. This provides certainty and predictability to the Bureau and market participants that the anti-competitive conduct will not be resumed. In some cases the Bureau may seek compensation for investigative costs as part of a consent agreement. Additionally, the Bureau may seek administrative monetary penalties in consent agreements, where appropriate.

B. Orders of the Competition Tribunal

99. Where the Bureau is satisfied that the evidence supports an application to the Tribunal under section 79 and the Bureau cannot resolve a case on a consensual basis, or where a consensual remedy is not considered appropriate in the circumstances, the Bureau may make an application to the Tribunal for a remedial order.[61]

100. Where the Tribunal finds that the elements of section 79 are met, the Act grants the Tribunal broad discretionary remedial powers to address the anti-competitive conduct in question. This includes the ability to impose both behavioral and structural remedies, varying from prohibition orders (subsection 79(1)), prescriptive orders requiring that certain corrective action be taken (subsection 79(2)) and the imposition of administrative monetary penalties (subsection 79(3.1)).

i. Prohibition and Prescriptive Orders

101. Pursuant to subsection 79(1), the Tribunal may issue an order prohibiting a respondent from engaging in the impugned practice of anti-competitive acts. In addition or alternatively, if the Tribunal finds that an order prohibiting the practice is not likely to restore competition in the affected market, subsection 79(2) provides that the Tribunal may issue an order directing the respondent to take any such actions as are reasonable and necessary to overcome the effects of the practice of anti-competitive acts, including the divestiture of assets or shares.[62] Other actions may include, for instance, changes to contractual terms, or the establishment of a corporate compliance program. The Bureau typically views prohibition and prescriptive orders as complementary and, where appropriate, may seek orders that both prohibit the anti-competitive conduct and direct the respondent to take positive steps or actions as are necessary to restore competition in the market.

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61 The Commissioner is the only party that may make applications to the Tribunal under section 79. See **subsection 79(1) of the Act**.

62 Subsection 79(2) permits the Tribunal to grant both prescriptive behavioural remedies (e.g., compelling a respondent to undertake certain mandatory conduct) and structural remedies (e.g., the divestiture of assets). The Bureau does not seek structural remedies to abuses of dominance in the vast majority of circumstances, but may consider doing so where an abuse of dominance causes structural changes in a market such that competition cannot be restored by a behavioural remedy alone. For example, where a practice has removed effective pre-existing competitors from a market where barriers to entry (that are not created or enhanced by the abuse of dominance) have increased over time with the result that new entry is not feasible, the Bureau may seek a divestiture that would permit a new entrant to be a viable competitor. This could either be in lieu of or in addition to a prohibition order under subsection 79(1) and/or a prescriptive behavioural remedy under subsection 79(2).

102. Failure to comply with an order rendered under section 79 (other than subsection 79(3.1)) or a consent agreement registered with the Tribunal under section 105 is a criminal offence.[63]

ii. Administrative Monetary Penalties

103. Where the Tribunal issues an order pursuant to subsections 79(1) and/or 79(2) of the Act, it may also, pursuant to subsection 79(3.1), order the respondent to pay an administrative monetary penalty ("AMP"). Such a penalty may not exceed $10 million for the first order, or $15 million for each subsequent order. The purpose of an AMP in an abuse of dominance case is to promote practices by the person from whom an AMP is sought that are in conformity with the purposes of section 79, not to punish the respondent for the anti-competitive conduct.[64] Failure to pay an AMP by a respondent may be enforced civilly as a debt due to the Crown.[65]

104. The Bureau generally considers AMPs as a complement to other remedies available under section 79 that are designed to restore competition. Given their purpose to promote practices by the dominant firm that are in conformity with the purposes of section 79 the Bureau's decision to seek AMPs and their amounts will depend to a great extent on the facts specific to each case.

105. When assessing whether an AMP is appropriate, the Bureau will consider factors such as: (i) the respondent's willingness to collaborate in a timely manner with the Bureau in the context of the investigation or inquiry, including to immediately cease the impugned conduct when the Bureau raises competition concerns; (ii) the respondent's history of compliance with the Act; and (iii) whether the evidence suggests the respondent intended not to comply with the Act, or showed a wanton or reckless disregard for the Act.

63 See section 66 of the Act.

64 See subsection 79(3.3) of the Act.

65 See section 79.1 of the Act.

106. When the Bureau determines that an AMP is warranted in the circumstances, the determination of its amount will be guided by the aggravating and mitigating factors set out in subsection 79(3.2) of the Act:

- The effect on competition in the market;
- The gross revenue from sales affected by the practice;
- Any actual or anticipated profits affected by the practice;
- The financial position of the person against whom the order is made;
- The history of compliance with the Act by the person against whom the order is being made; and
- Any other relevant factor.

107. The amount of an AMP is to be determined based on the totality of the relevant considerations in the circumstances; no single factor is determinative.

108. In cases where an AMP is sought, the Bureau will be mindful to seek AMPs of the quantum necessary to ensure that AMPs do not merely become the "cost of doing business" for a dominant firm engaging in anti-competitive conduct, within the statutory limits, while also ensuring that they are not excessive or disproportionate in the circumstances and serve their statutory purpose, i.e., to promote conduct that is in compliance with the purposes of the abuse of dominance provisions.

109. The Bureau is guided by similar considerations and factors when determining whether to include an AMP in consent agreements in respect of abuse of dominance and in establishing the amount.

05 Illustrative Examples

110. The following examples are designed to illustrate the analytical framework that may be applied by the Bureau in the enforcement of section 79. These examples are not intended to provide an exhaustive catalogue of all conduct that may raise issues under section 79, and depending on the facts of any individual case the Bureau may depart from the analytical approach set out below. As with these Guidelines generally, the Bureau's discussion of the examples below does not replace the advice of legal counsel and is not intended to restate the law or to constitute a binding statement of how the Commissioner will exercise discretion in a particular situation. The enforcement decisions of the Commissioner and the ultimate resolution of issues will depend on the particular circumstances of the matter in question.

A. Example 1 – Mere Exercise of Market Power

111. HO3 and SANTA are firms that compete in respect of the supply of Santa hats in Canada. These two firms are the most important players in the market with market shares of 65 percent and 20 percent for HO3 and SANTA respectively. High barriers to entry make it difficult for a new entrant to enter the market. Recently, HO3 unilaterally raised the prices for the Santa hats it sells in Canada by over 250 percent. The Bureau has received complaints that HO3 has abused its dominant position.

Analysis

112. Although it is necessary for a firm to possess a substantial degree of market power in order to contravene section 79, this alone is not sufficient to raise issues under the abuse of dominance provisions of the Act. Even where a firm may be dominant, it must also be engaging in a practice of anti-competitive acts that gives rise to a substantial lessening or prevention of competition. The Bureau would not view HO3's price increase as an anti-competitive act as it does not exclude, predate, or discipline a competitor or a potential competitor. Further, because the price increase is a result of HO3's pre-existing market power, not a practice of anti-competitive acts, paragraph 79(1)(c) cannot be established.

B. Example 2 – Market Definition

113. DUTY is one of several manufacturers of heavy-duty drills in western Canada. During the last year, SMASH, a manufacturer with a great reputation in the market for high-end hammers, started marketing "hyper-duty" drills to retailers in western Canada. These "hyper-duty" drills are 20 percent more expensive than the ones offered by DUTY, but they are also 30 percent more powerful. SMASH, DUTY, and all other drill manufacturers in western Canada only sell their products through unaffiliated retail channels.

114. Different drill manufacturers operate in eastern Canada, and shipments of drills between the two regions are limited, accounting for approximately 5 percent of drills purchased in western Canada. The share of eastern Canadian produced drills purchased in western Canada has remained relatively stable despite price fluctuations between the two regions. However, within western Canada, prices generally follow each other across the region and shipments of drills are observed in response to price differentials.

115. SMASH has complained to the Bureau, alleging that DUTY has engaged in a practice of anti-competitive acts relating to certain of DUTY's contracting practices. As part of its complaint, SMASH has presented evidence that its costs, and consequently its prices, have increased as a result of DUTY's conduct, while the prices of DUTY and other traditional drills remained stable.

Analysis

116. This example will focus on product and geographic market definition.

117. To initially conceptualize substitutability, the Bureau would generally use the hypothetical monopolist test. In order to do so, the Bureau may seek data on substitution patterns between different drill types and manufacturers. In addition, the Bureau would seek information on qualitative factors relating to substitutability; as set out above, these include (i) functional interchangeability, (ii) views, strategies, behaviour and identity of buyers, (iii) trade views, strategies and behaviour (inter-industry competition), (iv) price relationships and relative price levels, and (v) switching costs. For

example, the Bureau would seek to examine if the additional power or higher cost from the "hyper-duty" drills prevents or limits substitution, or if the hyper-duty drills are interoperable with existing equipment. Such information may be sought from sources including contractors, retailers and other drill manufacturers.

118. In this instance, as all drill manufacturers only sell their products through retailers, the Bureau would likely seek to define a market relating to the sale of drills to retailers, rather than consumers. However, as substitution at the retail level could be informed by consumer demand, evidence on end-consumer preferences and substitution patterns may be relevant.

119. When defining markets for the purpose of section 79, it is necessary to assess substitutability at the price that would have prevailed absent the impugned conduct. In this case, the Bureau may accord particular weight to evidence of substitutability from before the period DUTY engaged in the alleged conduct. However, the Bureau would consider the evidence that the increase in price for "hyper-duty" drills was not correlated with an increase in price for traditional drills to be indicative that they are not in the same market.

120. Similarly, the Bureau would use the hypothetical monopolist test to examine the bounds of the geographic market, i.e., the extent of retailer switching from drill manufacturers in one region to manufacturers in another region. Generally, the Bureau would look at whether an area is sufficiently insulated from price pressures emanating from other areas so that its unique characteristics can result in its prices differing significantly in any period of time from those in other areas. Due to the pricing differentials with eastern Canada, different competitors, and limited imports that do not vary with the price differential, the Bureau would likely conclude that eastern Canada should not be included in the same geographic market as western Canada. The fact that drill manufacturers compete across western Canada and that prices and purchases track each other across the region would support the conclusion that western Canada is the appropriate geographic market.

C. Example 3 – Market Power

121. SUBSTANTIAL is Canada's premier supplier of toques. Toques are sold in specialized boutiques; although toque retailers usually stock several brands of toque, they do not typically sell unrelated products. SUBSTANTIAL has a market share of 40 percent. There are six other competitors who evenly account for the remainder of the market.

122. Information gathered by the Bureau suggests that a substantial number of consumers have a strong preference for SUBSTANTIAL's products, and only shop at retailers that stock them. Other customers do not share this preference, and are willing to consider other substitutes, but no other brand of toque attracts similar customer loyalty. Consumers view SUBSTANTIAL's products as key to establishing credibility as a toque boutique, and a retailer that does not carry SUBSTANTIAL toques will be significantly disadvantaged against its rivals as a result. For these reasons, SUBSTANTIAL is able to obtain considerably more favourable support from retail channels, including favourable placement and expenditure on promotional activities.

123. A competitor of SUBSTANTIAL has complained to the Bureau, alleging that SUBSTANTIAL has engaged in a practice of anti-competitive acts relating to SUBSTANTIAL's contractual terms with retailers which have excluded itself and other competitors. They have provided credible evidence that as a result of SUBSTANTIAL's practice, the price SUBSTANTIAL charges for toques has risen by more than 33 percent.

Analysis

124. The purpose of this hypothetical is to illustrate the Bureau's approach to assessing market power in the context of abuse of dominance. For the purposes of this analysis, the Bureau has already determined that the market is toques sold to retailers in Canada.

125. The Bureau will typically begin with an assessment of whether a firm holds a substantial degree of market power based on structural considerations. This involves determining the market and then assessing market shares and barriers to entry. In the absence of other evidence, based on these factors alone, the Bureau will not typically find dominance in cases where the allegedly dominant firm has a market share of less than 50 percent. However, in some cases, contextual factors may suggest that market shares may not be representative of the full extent of a firm's market power and may prompt further investigation by the Bureau.

126. In this case, evidence of SUBSTANTIAL's leverage over retail channels and the competitive impact of SUBSTANTIAL's actions would likely prompt further investigation. When assessing the extent to which SUBSTANTIAL has commercial leverage over its retail channels, one factor the Bureau would consider is whether SUBSTANTIAL is willing and able to discipline retailers that do not comply with SUBSTANTIAL's terms, or if the threat of punishment is sufficient to exert leverage over retailers. If SUBSTANTIAL is able to unilaterally demand and receive considerably more favourable terms than other suppliers or dictate the level of support other brands of toque receive, the Bureau may consider this an indicator of market power. A key element of the Bureau's analysis would be examining the underlying consumer demand for SUBSTANTIAL's products, and the amount of switching that would occur if the prices of SUBSTANTIAL's products increased notwithstanding any alleged anti-competitive acts. The Bureau may also consider that the evidence that SUBSTANTIAL's toque prices increased by more than 33 percent as a result of SUBSTANTIAL's alleged anti-competitive conduct suggests SUBSTANTIAL has market power.

127. Given these factors, the Bureau may conclude that SUBSTANTIAL substantially or completely controls a market within the meaning of paragraph 79(1)(a), that is, it possesses a substantial degree of market power, notwithstanding SUBSTANTIAL's market share of 40 percent.

D. Example 4 – Joint Dominance

128. BUDDY, PAL, and CHUM are manufacturers of tandem bicycles, who sell their products through retailers. All three are roughly the same size, and each has a market share of approximately 33 percent. These market shares have remained stable over the past five years. Evidence suggests that BUDDY, PAL, and CHUM do not materially attempt to solicit the customers of the others, and there is very little customer switching between the firms.

129. BUDDY, PAL, and CHUM engage in long-term contracts with retailers that include automatic renewals, significant liquidated damages clauses in the event of early termination, and meet-or-release clauses that apply for a period subsequent to a contract being terminated in accordance with its conditions. These contracts both limit incentives for BUDDY, PAL, and CHUM to compete among each other and make it more difficult for new entrants to acquire customers.

130. FRIENDLY has unsuccessfully attempted to enter the market for tandem bicycles. Despite offering lower prices, FRIENDLY was unable to secure a sufficient number of customers due to the contracting practices of BUDDY, PAL, and CHUM. Without the ability to realize the economies of scale necessary to compete with the incumbents, FRIENDLY was forced to abandon its efforts to enter the market.

Analysis

131. This hypothetical will focus on assessing whether BUDDY, PAL, and CHUM are jointly dominant, rather than the other elements of section 79. The Bureau has already established that the product market is tandem bicycles, and the geographic market is Canada.

132. First, the Bureau would seek to assess whether firms outside the allegedly dominant group, either existing competitors or potential entrants, can discipline any exercise of market power by BUDDY, PAL, or CHUM. In this case, as there are no other firms in the market, the focus of this assessment would be on potential entrants. The Bureau would consider the barriers to entry that exist, as well as the history of failed entry by FRIENDLY. Unless the Bureau found that barriers to entry were low (including barriers created by the conduct at issue), the Bureau may conclude that potential entrants could not discipline the joint exercise of market power by the incumbents.

133. The Bureau would then examine if competition between BUDDY, PAL, and CHUM is sufficient to prevent a joint exercise of market power to a substantial degree. Relevant information to this assessment includes factors such as the stability of market shares over time, the lack of active solicitation of the others' clients, and low customer switching, which would suggest that BUDDY, PAL, and CHUM jointly possess a substantial degree of market power. That BUDDY, PAL, and CHUM have adopted similar contractual terms may be relevant to this analysis to the extent they lessen the vigour of competition among the three, and therefore facilitate the joint exercise of market power.

134. As a result, the Bureau could conclude BUDDY, PAL, and CHUM are jointly dominant in the market for tandem bicycles in Canada, satisfying the requirement of paragraph 79(1)(a).[66]

E. Example 5 – Predatory Pricing

135. CHATEAU and DOMAINE are two Canadian maple-infused ice wine producers. Both produce only one type of wine, which is unique to these two vineyards. Indeed, both are located on a major hill in Gatineau with a particular micro-climate that cannot be found anywhere else in the world and this gives their products a distinctive taste which is sought after by connoisseurs.

136. Following a change in the leadership of CHATEAU, last year its new management substantially increased production and now offers customers a $40 rebate to the regular $50 price on each bottle of this year's vintage of its classic ice wine. Following this, DOMAINE contacted the Bureau alleging that this constitutes predatory pricing.

Analysis

137. Allegations of predatory pricing are examined under section 79 of the Act. Predatory pricing occurs when a firm deliberately prices below its own costs in order to eliminate or discipline existing rivals or to deter entry. This can substantially lessen or prevent competition when the firm engaging in the predation can subsequently recoup its losses by charging prices above the level that would otherwise have prevailed. For the purposes of this example, assume that the wines of CHATEAU and DOMAINE constitute the product market, the geographic market is Canada, and that CHATEAU holds a substantial degree of market power within that market.

138. As a pre-condition for predatory pricing, the Bureau considers it necessary for the relevant products to be priced below their average avoidable costs. Regarding this particular fact situation, a relevant initial way to assess the validity of DOMAINE's concerns would be to seek information from DOMAINE on its own costs and profitability. If CHATEAU's price is above DOMAINE's own costs, the Bureau would conclude that DOMAINE is not likely to be excluded by the pricing strategy and as a result, the requirements of paragraph 79(1)(c) are not likely met. Further, this would cast doubt on the assertion that CHATEAU is pricing below its own costs.

139. When assessing CHATEAU's average avoidable costs, the Bureau's focus will be on determining those costs that would have been avoided had CHATEAU not produced and sold the wine subject to the pricing strategy, including any opportunity costs. For simplicity, assume that there are four categories of costs that CHATEAU incurs:

[66] In addition to the above factors, the Bureau would also consider any other relevant evidence that a substantial degree of market power exists on the part of BUDDY, PAL, or CHUM, such as direct evidence of market power, or an ability to exclude.

- Bottles: CHATEAU purchases bottles shortly before bottling a given vintage based on the quantity it needs;

- Barrels: CHATEAU has a fixed stock of aging barrels, which is larger than what it typically requires at any time and CHATEAU rents excess barrels out to other vineyards;

- Labour: CHATEAU has a permanent staff who can only be fired in extreme circumstances, and hires seasonal labour to assist with grape planting, harvesting, processing, and bottling; and

- Land: CHATEAU is 68 years into a 100 year lease for the land the vineyard is situated on, cannot increase or reduce the amount of land it leases, and cannot use the land for any other purpose.

140. Because the quantity of bottles CHATEAU purchases varies based on the amount of wine CHATEAU produces, the Bureau would view this as an avoidable cost. Conversely, because CHATEAU cannot increase or reduce the amount of land it leases, the Bureau would not view land as an avoidable cost regardless of what share of CHATEAU's total costs the lease represents.

141. Because CHATEAU rents out barrels to other vineyards, when it uses them to age its own wine CHATEAU incurs an opportunity cost for the foregone rent it otherwise would have received. As a result, this foregone rent becomes an avoidable cost even if CHATEAU would not have purchased additional barrels.

142. Certain elements of CHATEAU's labour costs would likely be avoidable, while others may not be. Any seasonal labour CHATEAU retained for the purposes of producing the wine subject to the pricing strategy would be avoidable. If CHATEAU would not have hired any additional permanent employees to produce the wine, and as CHATEAU is limited in its ability to terminate permanent employees, these costs would not be avoidable, depending on the duration of the pricing strategy. To illustrate, if the pricing occurs for a short period, CHATEAU may not be able to alter its costs related to permanent employees. However, if it persists for a longer time such that permanent employees may quit or retire and CHATEAU would have discretion as to whether to hire replacements, permanent labour costs may become avoidable.

143. The Bureau would typically also seek to determine if there is credible evidence of a legitimate business objective on the part of CHATEAU – e.g., if they were meeting a price set by a competitor, selling excess, obsolete or perishable inventory, or seeking to induce customers to try a new product.

144. Having determined CHATEAU's avoidable costs, the Bureau would then compare this to the price of the wine subject to the pricing strategy. In the absence of a credible business justification, if CHATEAU is pricing below its average avoidable cost, the Bureau would likely conclude that CHATEAU has engaged in a practice of anti-competitive acts.

145. In addition, even where a firm is pricing below its average avoidable costs, in order to substantially lessen or prevent competition and thereby raise issues under the Act it must be likely for a firm to recoup the losses it incurred through its pricing strategy. If any attempt to subsequently raise prices would be thwarted by timely new entry, re-entry, or remaining competitors, the below cost pricing will not give rise to a substantial lessening or prevention of competition. In such cases, if the dominant firm successfully raises prices, and barriers prevent new entry, re-entry or expansion of existing competitors from being sufficiently timely or sufficient to discipline the exercise of market power on the part of the dominant firm, competition will be substantially prevented or lessened.

146. Barriers to entry may be created or strengthened by the predation. For example, by developing a "reputation for predation" a dominant incumbent may create the perception that entry will be unprofitable, deterring actual or potential entrants.

147. In this case, the Bureau would evaluate if any attempt by CHATEAU to raise prices and exercise market power would be thwarted by re-entry by DOMAINE, or by new entry. In this case, if re-entry by DOMAINE is unlikely or would not discipline CHATEAU's market power and a new entrant would be unable to obtain the land, assets, or know-how necessary to produce a competing wine, or would face significant reputational barriers due to being an unproven entrant that would prevent it from disciplining CHATEAU's market power, the Bureau may conclude that recoupment is possible and that the conduct substantially lessens or prevents competition.

F. Example 6 – Exclusive Dealing

148. A panopticon is a consumer electronic device that has become ubiquitous since its introduction three years ago. Most major consumer electronics manufacturers started developing their own panopticons and are competing to offer the best panopticons to consumers with the most advanced features.

149. Panopticons collect a significant volume of data on their users, including location and spending habits. Realizing the value of this data, several companies, known as panopticon data aggregators, started buying panopticon data directly from the panopticon manufacturers in order to analyze it and monetize the intelligence mined from the data. One of the key uses of aggregated panopticon data is providing insights into consumer preferences and purchases for advertising and marketing purposes.

150. In Canada, unlike in the United States where there are three major panopticon data aggregators, only one firm is offering these services. That firm, named THOTH, has been collecting panopticon data for the last two years and uses this data to enhance the capabilities of its algorithm, making its product even more desirable to customers. Having two years of Canadian panopticon data in its algorithm gives THOTH a significant competitive advantage over any entrant in the market for panopticon data aggregation in Canada. Further, THOTH collects data on how its customers use THOTH's aggregated data, which permit it to further improve the quality of its algorithm.

151. Over the last year, THOTH has started signing new ten-year contracts with all its suppliers of panopticon data in Canada. These contracts include significant monetary penalties for early termination, as well as bonus payments for providing THOTH exclusive access to data. THOTH claims that these contractual terms are necessary in order for it to recoup the significant investments it has made in integrating the data from its suppliers into its algorithm. Further, THOTH claims that the exclusivity payments incentivize data suppliers to technologically integrate themselves with THOTH's platform, increasing the quality of data THOTH collects and improving the analysis it can provide to customers.

152. ENKI, THOTH's largest competitor in the United States, has complained to the Bureau that because of these contractual terms ENKI cannot secure the data it would require to enter the Canadian market and compete with THOTH.

Analysis

153. For the purposes of this hypothetical, assume that the Bureau has already defined a product market around panopticon data aggregation in Canada, and that THOTH is dominant in that market.

154. When assessing if THOTH has engaged in a practice of anti-competitive acts, the Bureau would likely focus its analysis on the payments for exclusive access to panopticon data.[67] In particular, the Bureau would seek to determine if the purpose of the payments was to foreclose access to panopticon data in order to exclude rivals.

155. When assessing the purpose of the contractual terms, the Bureau may examine evidence relating to the negotiation of the contractual terms. This analysis may consider whether the contractual terms were included at the request of THOTH or the suppliers. In the latter case, the Bureau may assess THOTH's intent in agreeing to the supplier's request, or any modifications to the supplier's request that may have been made at the behest of THOTH.

156. As part of the Bureau's investigation, in addition to seeking any subjective evidence of intent on the part of THOTH, the Bureau may seek to determine if excluding ENKI was a reasonably foreseeable consequence of the contractual terms. This may include gathering information on the extent to which substitutes exist for the data suppliers subject to the THOTH contracts, whether additional suppliers could enter or ENKI could self-supply with data, and if the payments for exclusivity have the effect of inducing some or all data suppliers to not deal with ENKI. The Bureau would also assess the extent to which ENKI requires data from all suppliers to be viable in the market. The Bureau may also examine whether, even without the exclusivity payments, it was reasonably foreseeable that panopticon data suppliers would not have supplied data to ENKI. If the contractual terms have the effect of preventing a sufficient number of data suppliers from dealing with ENKI and there are no viable alternatives, the Bureau could conclude that a negative exclusionary effect on a competitor was reasonably foreseeable.

[67] Because the contractual terms have been consistently inserted into ten-year agreements with data suppliers, the Bureau would consider THOTH to be engaged in a practice.

157. The Bureau may also assess any relevant business justifications for the contractual terms advanced by THOTH. Here, it argues that the exclusivity payments incentivize beneficial technological integration. If, for example, there was no contemporaneous evidence at the time the contractual terms were entered into that the payments would improve technological integration and thereby product quality, the Bureau would be unlikely to find THOTH's justification credible. Even if there is some evidence of the benefits of the payments, if there was contemporaneous evidence suggesting THOTH considered other options to achieve similar outcomes through less restrictive means (e.g., contracting for similar services instead of requiring exclusivity) the Bureau may not consider THOTH's business justification persuasive.

158. The Bureau may also consider whether THOTH's exclusivity payments made economic sense but for the exclusion of competitors. This would involve trading off the costs of the exclusivity payments against any revenues that would be derived from benefits other than exclusion (e.g., increased sales of aggregated panopticon data due to higher quality, if any). In the absence of demonstrated revenues that do not depend on exclusion, the Bureau could consider this an indicator that the exclusivity payments have an anti-competitive purpose.

159. The Bureau would then consider whether the contractual terms substantially lessened or prevented competition in the market for panopticon data aggregation, i.e., if the contractual terms permit THOTH to exercise materially greater market power in the past, present, or likely in the future.

160. In this circumstance, the Bureau would seek to determine the extent to which barriers to entry are the result of THOTH's contractual terms, as compared to characteristics of the market itself. For instance, in an industry characterized by network effects, the extent to which barriers to entry already exist must be taken into account when assessing the effect of the clauses on competition. Here, THOTH's superior algorithm resulting from two years of panopticon data aggregation and customer use data may create sufficiently strong barriers that the contractual terms have no incremental effect.

161. The Bureau would seek to determine if, in the absence of THOTH's contractual terms, entry would be timely, likely, and sufficient to discipline the market power of THOTH. In order to assess the effects of the contractual terms, the Bureau may seek information on the state of competition in the United States where there are no exclusivity clauses, and the views of other potential entrants. If evidence indicated that entry would be unlikely because of the market structure even in the absence of such clauses, it would make the Bureau significantly less likely to conclude that there has been, is, or is likely to be a prevention of competition resulting from the clauses.

162. If the contractual terms are having the incremental effect of deterring entry, the Bureau would seek to assess the competitive significance of that entry. This may include examining evidence on the relative state of competition in markets for panopticon data aggregation where no such exclusivity clauses with suppliers exist, such as the United States. If evidence indicated that prices paid for panopticon data would be substantially lower, quality of services higher, or that there would be substantially more innovation in the absence of the contractual terms, the Bureau could conclude that THOTH's conduct has substantially prevented competition.

G. Example 7 – Tied Selling

163. GORDIAN produces hitches, which are used in a variety of industrial applications. Use of a hitch requires rope, which quickly degrades and often needs to be replaced.

164. As late as two years ago there were four different producers of rope, including GORDIAN. At that time a rival producer, ALEXANDER, began developing plans to introduce a competing product to GORDIAN's hitches. ALEXANDER planned to leverage synergies between hitch and rope production to reduce costs and offer hitches at a price 20 percent below GORDIAN. Shortly afterward, GORDIAN introduced a policy requiring that only GORDIAN rope may be used with its hitches in order for the hitch to qualify for warranty coverage. Following this, the vast majority of hitch users switched to GORDIAN rope. As a result ALEXANDER and other third party rope manufacturers exited the market, and, as ALEXANDER was no longer able to rely on production efficiencies between hitches and rope, abandoned its efforts to compete with GORDIAN hitches.

165. GORDIAN claims that this policy was implemented because of low quality third party rope causing damage to its hitches, increasing GORDIAN's costs to provide service and lowering the reputation of its products.

Analysis

166. For the purposes of this hypothetical, assume that the Bureau has already defined a product market around hitches, and that GORDIAN is dominant in that market. Further, subject to hitches and rope being separate products (as discussed below), assume that the Bureau has defined rope to be a product market. In both cases, assume that the geographic market is Canada.

167. The Bureau would seek to determine whether the alleged tying and tied products are in fact separate products. A central question in the inquiry is the extent to which separate customer demand exists for the tying and tied products. The Bureau may also consider efficiencies that arise from a tie; if, for example, implementing a tie gives rise to efficiencies such that it is not commercially viable to offer the products separately the Bureau could not conclude the tying and tied products to be separate notwithstanding consumer demand.

168. In this case, when evaluating whether separate demand exists, the Bureau may consider the history of hitches and rope being purchased from different manufacturers, as well as the views of current and potential rope purchasers. Based on these facts, the Bureau could conclude that separate demand exists.

169. The Bureau could also consider whether implementing the tie gives rise to efficiencies such that it is not practical to offer hitches and rope as separate products. Because the economies of scope between rope and hitches rely on their joint production rather than the tie, the economies of scope would not be considered as part of this analysis. Here, the Bureau could consider the history of the two products being sold separately to be dispositive, and conclude that hitches and rope are separate products.

170. The Bureau may then turn to assessing whether GORDIAN's purpose in implementing the tie was anti-competitive; in this case, focussing on whether the tie was intended to exclude one or more competitors in the market for rope . This would involve examining evidence of GORDIAN's subjective intent in implementing the tie, as well as the reasonably foreseeable effects of the tie.

171. The Bureau would typically examine the extent to which the tie is binding, that is, the extent to which the tie was likely to divert demand in the market for rope to GORDIAN. For instance, if hitch users can readily turn to effective substitutes for GORDIAN's warranty services at a sufficiently low cost, exclusion from the change to the warranty policy is not likely to be reasonably foreseeable (and similarly, if the tie is not binding, it is unlikely to prevent or lessen competition substantially). The Bureau would also examine the extent to which entry would be effective both into the market for hitches in the absence of economies of scope between hitches and rope, as well as the feasibility and effectiveness of entry into both markets simultaneously.

172. The Bureau would also consider any business justifications posited by GORDIAN. In this case, this may include gathering evidence on the extent to which third party rope caused hitch breakdowns prior to the tie, whether breakdowns have decreased following the tie, and if customer satisfaction with hitches has improved.

173. If subjective or objective evidence suggests the tie was instituted with exclusionary intent, and that evidence in support of the business justification was not compelling, the Bureau could conclude that GORDIAN has engaged in a practice of anti-competitive acts.

174. The Bureau would then consider whether the tie has, is, or is likely to cause a substantial lessening or prevention of competition in either the market for hitches or the market for rope. For example, if the Bureau concluded that the tie had raised barriers to entry in the market for hitches by denying economies of scope with rope production, the Bureau could conclude that there has been a substantial prevention or lessening of competition.

H. Example 8 – Trade Association Rules

175. SOL is a provincial trade association of solar panel manufacturers. Among other activities, SOL coordinates industry quality and performance standards for exclusive use of its members, and certifies compliance with these standards. Purchasers of solar panels have come to recognize and demand the certification SOL provides, and uncertified solar panels see markedly lower sales. Because of the significant benefits these standards provide, virtually all solar panel manufacturers in the province are members of SOL. There are similar trade associations to SOL in other provinces, who engage in similar activities. SOL is purely a trade association: it does not produce solar panels, and has not been provided with any powers or regulatory role by any federal or provincial statute.

176. There are many solar panel manufacturers that are members of SOL, and no individual member has a market share of more than 5 percent. The past several years have seen various solar panel manufacturers enter and exit the market.

177. SUNNY is a highly successful solar panel manufacturer outside the province in which SOL operates. Unlike other solar panel manufacturers who sell homogenous solar panels through traditional retail channels, SUNNY has pursued a business model where customers may order personalized solar panels through the internet, which are then shipped directly. Many consumers consider SUNNY's solar panels to be more convenient, of higher quality relative to those of its competitors, but at a comparable cost. SUNNY has grown rapidly in its native province, and is considering expanding its operations across the country.

178. Around the time SUNNY began rapidly expanding, SOL passed rules prohibiting its members from selling customized products directly to consumers. SOL claims that because customized solar panels are more varied, if they bypass traditional retail channels (where they can be more readily monitored) they cannot be subject to the same level of testing and cannot be certified as part of the standard for panels established by SOL. SUNNY has complained to the Bureau, stating that it wishes to begin operating in SOL's province, but is prevented due to the rules of SOL. SUNNY claims that without certification by SOL, demand for SUNNY's products will be markedly reduced and as a result its entry based on its current business model will not be viable.

Analysis

179. For the purpose of this hypothetical, assume the Bureau has determined the market to consist of solar panels sold in the province in which SOL operates.

180. Having defined the market, the Bureau would assess whether SOL substantially or completely controls that market. Although the Bureau may seek to understand if substitutes exist for the services of SOL – for example, if alternate certifications exist that SOL's members can effectively substitute for SOL's – the Bureau may not engage in a separate market definition exercise around the services of SOL or assess its market power in that second market. However, the existence and feasibility of substitutes for SOL's services may be relevant in assessing if SOL holds a substantial degree of market power in solar panels, the reasonably foreseeable effects of SOL's restrictions, and if such restrictions give rise to a substantial lessening or prevention of competition.

181. When determining whether SOL substantially or completely controls the market for solar panels, the Bureau could consider the extent to which SOL can influence factors such as price, quality, variety, service, advertising or innovation in the market for solar panels. This would typically include an examination of whether membership in SOL and access to its certification is commercially necessary to compete in the market, and the extent to which SOL can enforce its rules on its members. If, for example, SOL can effectively exclude competitors or types of competition from the market, the Bureau could consider this requirement satisfied. In this case, the Bureau may seek to assess the extent to which consumer demand for a manufacturer's solar panels depends on SOL's certification. If consumer demand was sufficiently reduced for uncertified solar panels as to make it infeasible to compete, the Bureau could conclude SOL has a substantial degree of market power.

182. The Bureau will then seek to understand if SOL has engaged in a practice of anti-competitive acts. As SOL does not compete in the market for solar panels, the Bureau may seek to determine if SOL has a plausible competitive interest in negatively affecting competition in the market for solar panels. As SOL is a trade association that acts in the interests of its members, the Bureau would likely conclude that it has such a competitive interest.

183. The Bureau would seek to evaluate the purpose of the rules adopted by SOL. This may include examination of contemporaneous evidence of SOL's intent, such as documents or statements by SOL's officers, that speak to the intent behind SOL's rule changes. The Bureau may also consider whether exclusion of business models such as SUNNY's was a reasonably foreseeable consequence of the rules adopted by SOL. The Bureau would also consider any business justifications put forward by SOL, evaluate their credibility, and determine whether these business justifications outweigh any evidence of anti-competitive intent. When evaluating the justification that individualized products may not conform to the standards set by SOL, the Bureau may evaluate the experience from areas where comparable restrictions are not adopted and the extent to which SOL conducted any studies to support the need for its restrictions. The Bureau may also have regard to whether the restrictions made economic sense, but for the exclusion of disruptive competition.

184. The Bureau would then seek to evaluate whether the restrictions give rise to a substantial lessening or prevention of competition. In doing so, the Bureau would consider whether there would be substantially greater competition among the members of SOL in the absence of the restrictions. Notably, the Bureau would not consider the relatively small market shares of the individual members of SOL or entry and exit (i.e., the absolute level of competition in the market), as dispositive in this regard. The Bureau's concern could be that the rules of SOL exclude or impede entrants (or potential entrants), as well as innovation among the members of SOL, leading to reduced dynamic competition. Relevant factors would include if the restrictions increased barriers to entry and expansion, whether the restrictions reduced the range of solar panels offered or their quality, and whether the restrictions have reduced innovation. The Bureau may find natural experiments in other markets persuasive, as well as the projections of businesses regarding the services they could offer but for the restrictions. The Bureau would also seek to assess whether other members of SOL would be offering higher quality services, be more innovative, or otherwise be engaging in more vigorous competition in the absence of the restrictions.

I. Example 9 – Disciplinary Conduct (1)

185. STATIC is Canada's largest provider of Secured Lending Cross-swaps (SLCs), a type of consumer-facing financial product, selling 60 percent of all SLCs in Canada. STATIC has one competitor, DYNAMIC, who accounts for the remaining 40 percent of sales. Since the entry of STATIC and DYNAMIC, significant tax incentives for the industry have been terminated and regulatory requirements for new entrants were increased, making new entry prohibitively difficult.

186. Competitive conditions in the SLC market – market shares, fee levels, and service offerings – have remained generally stable over the past decade. Documents gathered by the Bureau suggest that each market participant has historically realized that they benefit from less vigorous competition between each other, and have not traditionally attempted to solicit each other's customers, reduced their prices, or improved their service offerings.

187. Six months ago, DYNAMIC hired a new CEO who publically stated that DYNAMIC would begin a new program of customer acquisition, cutting fees by 10 percent and developing a new and more convenient smartphone application for customers to monitor and manage their SLCs. Shortly thereafter, STATIC launched a second branding of SLCs, QUANTIFY, through which STATIC began selling SLCs at a 70 percent discount to regular fees. After one month, DYNAMIC announced it would continue with its pricing; STATIC immediately further dropped the fees of the QUANTIFY brand to 20 percent of historical levels, announcing that it would continue to offer these fees as long as DYNAMIC continued with its customer acquisition program. The following month, DYNAMIC's CEO stated they would abandon their customer acquisition program, citing changed competitive conditions. STATIC withdrew the QUANTIFY brand from the market.

188. Following a complaint to the Bureau and a preliminary investigation, evidence indicates that STATIC was not pricing below its average avoidable costs at any point. However, internal correspondence and memos indicated that, through launching QUANTIFY, STATIC intended to punish DYNAMIC for adopting a new fee strategy and deter DYNAMIC from continuing its low fees, rather than simply matching or beating DYNAMIC's pricing. STATIC has told the Bureau it was simply a pro-competitive, aggressive response to DYNAMIC's pricing.

Analysis

189. Assume the Bureau has defined the market as SLCs sold in Canada, and concluded that STATIC holds a substantial degree of market power.

190. When assessing if STATIC's conduct is an anti-competitive act, the Bureau may accord particular weight to subjective evidence of intent, in order to distinguish a disciplinary act from aggressive competition on the merits. In particular, the Bureau may look for evidence that, in launching QUANTIFY, STATIC was attempting to punish DYNAMIC for its customer acquisition program, and restore market conditions to the historical status quo. When evaluating the overarching purpose of STATIC's conduct, the Bureau could also consider documentary evidence that other competitive responses on the part of STATIC would have been profitable had DYNAMIC not abandoned its customer acquisition program.

191. If the Bureau were satisfied that STATIC's conduct constituted a practice of anti-competitive acts, the Bureau would seek to determine if it caused a substantial lessening or prevention of competition. This could involve assessing the fee levels that would have likely prevailed if STATIC had adopted a different response and DYNAMIC had persisted in its customer acquisition strategy, as well as any non-price effects from DYNAMIC abandoning its new smartphone application.

J. Example 10 – Disciplinary Conduct (2)

192. WILDERNESS is the largest retailer of outdoor equipment in Canada, and sells products primarily online. Due to advantages such as sophisticated recommendation algorithms driven by consumer data, WILDERNESS enjoys significant customer loyalty. WILDERNESS is well known for using algorithms and the automated collection of data to monitor and respond to market trends.

193. For the past three years, WILDERNESS has sold over 85 percent of tents purchased in Canada. There are two producers of tents, YURT and BIVOUAC.

194. FRONTIER is a rival e-commerce retailer that has recently commenced operations in Canada, and has begun selling tents, produced by both YURT and BIVOUAC. To date, FRONTIER has made minimal inroads to the Canadian market and at present facilitates sales of only 4 percent of tents.

195. Until recently, prices for tents on FRONTIER's platform have been comparable to those on WILDERNESS's. In the past few months FRONTIER has begun competing more aggressively on sales of tents, offering discounts up to 20 percent below WILDERNESS's prices. However, when FRONTIER began doing so, both YURT and BIVOUAC found that orders of their products were being shipped substantially slower to customers by WILDERNESS, and their products featured notably less favorable placement on WILDERNESS's website. Although WILDERNESS has not confirmed that this is the direct result of FRONTIER's pricing behavior, both YURT and BIVOUAC have taken steps to prevent FRONTIER from undercutting WILDERNESS on tents. When they did so, previous service levels and website placement with WILDERNESS resumed.

196. FRONTIER has complained to the Bureau in relation to WILDERNESS's conduct.

Analysis

197. For the purposes of this hypothetical, assume that the Bureau has defined a relevant market that consists of the retail sale of tents in Canada, and that the Bureau has concluded that WILDERNESS has a substantial degree of market power in that market.

198. Depending on the facts and evidence the Bureau could evaluate WILDERNESS's conduct as either exclusionary or disciplinary, or both. To the extent that WILDERNESS intended to increase FRONTIER's costs in order to make FRONTIER a less effective competitor in the market for tents, the Bureau may view WILDERNESS as engaging in exclusionary conduct. Alternatively, if, for example, WILDERNESS intended to deter FRONTIER from competing more vigorously without affecting its ability to compete, the Bureau may view this as disciplinary conduct.

199. In either case, to evaluate FRONTIER's claims, the Bureau may seek evidence from WILDERNESS with respect to the operation of its monitoring algorithms, fulfillment services, and decisions with respect to website placement, including the extent to which sales of YURT and BIVOUAC's products were indeed contingent on FRONTIER's lower pricing.

200. In order to evaluate if WILDERNESS's conduct gives rise to a substantial lessening or prevention of competition, the Bureau would seek evidence that but for the impugned conduct, prices would be lower in the market for tents. This would likely involve examining the extent to which FRONTIER would lower its prices in the absence of the impugned conduct. As part of this analysis, the Bureau would likely analyze the extent to which YURT and BIVOUAC are impacted by WILDERNESS's conduct, the causal impact of WILDERNESS's conduct on YURT and BIVOUAC's decision to prevent FRONTIER from undercutting WILDERNESS, as well as the extent to which FRONTIER would capture a significant share of WILDERNESS's former consumers if WILDERNESS continued to degrade its quality of service in relation to tent orders. The Bureau would also assess the duration of the lessening or prevention of competition; for example, if FRONTIER was engaging in promotional pricing for a limited period of time with little lasting benefit to FRONTIER's ability to compete with WILDERNESS, the Bureau would be less likely to conclude competition is substantially prevented or lessened.

Full citations of judicial decisions

Air Canada:
Commissioner of Competition v Air Canada, 2003 Comp Trib 13

Canada Pipe CT:
Commissioner of Competition v Canada Pipe, 2005 Comp Trib 3

Canada Pipe FCA 1:
Canada (Commissioner of Competition) v Canada Pipe Co, 2006 FCA 233, leave to appeal refused (10 May 2007).

Canada Pipe FCA 2:
Canada (Commissioner of Competition) v Canada Pipe Company Ltd, 2006 FCA 236, leave to appeal refused (10 May 2007).

Direct Energy:
The Commissioner of Competition v Direct Energy Marketing Limited, 2015 Comp Trib 2

Hillsdown:
Canada (Director of Investigation and Research) v Hillsdown Holdings Ltd (1992), 41 CPR (3d) 289 (Comp Trib)

Laidlaw:
Canada (Director of Investigation and Research) v Laidlaw Waste Systems Ltd (1992), 40 CPR (3d) 289 (Comp Trib)

NutraSweet:
Canada (Director of Investigation and Research) v NutraSweet Co (1990), 32 CPR (3d) 1 (Comp Trib)

Tele-Direct:
Canada (Director of Investigation and Research) v Tele-Direct (Publications) Inc. (1997), 73 CPR (3d) 1 (Comp Trib)

Tervita:
Tervita v Canada (Commissioner of Competition), 2015 SCC 3.

TREB CT:
The Commissioner of Competition v The Toronto Real Estate Board, 2016 Comp Trib 7

TREB FCA 1:
Commissioner of Competition v Toronto Real Estate Board, 2014 FCA 29, leave to appeal refused (24 July 2014).

TREB FCA 2:
Toronto Real Estate Board v Commissioner of Competition, 2017 FCA 236, leave to appeal refused (23 August 2018).

Visa:
The Commissioner of Competition v Visa Canada Corporation and MasterCard International Incorporated, 2013 Comp Trib 10

Exhibit “S6”

This is Exhibit “S6” referred to in the Affidavit of Emily Seaby, sworn before me this 26th day of July, 2024.

A Commissioner for Taking Affidavits, etc.
Jon Wall

PRESS RELEASE 10 October 2022 Brussels 3 min read

Antitrust: Commission sends Statement of Objections to Teva over misuse of the patent system and disparagement of rival multiple sclerosis medicine

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The European Commission has informed Teva of its preliminary view that the company has breached EU antitrust rules by engaging in practices intended to delay competition to its blockbuster medicine, Copaxone. These consisted in artificially extending patent protection of Copaxone and by systematically spreading misleading information about a competing product with a view to hinder its market entry and uptake.

Executive Vice-President Margrethe **Vestager**, in charge of competition policy, said: *"Until today, there is not yet a treatment for the chronic illness of multiple sclerosis. So innovative medicines can make a major difference to patients' quality of life. Effective protection of intellectual property is key to this scientific progress. Our concern is that Teva may have misused the patent system to shield itself from competition. It may have spread misleading information to discredit its closest competitor, to the detriment of patients and public health systems across the EU."*

Teva is a global pharmaceutical company headquartered in Israel and operating through several subsidiaries in the European Economic Area. Teva's blockbuster medicine, **Copaxone**, is widely used for the treatment of multiple sclerosis and contains the active pharmaceutical ingredient glatiramer acetate over which Teva held a basic patent until 2015.

Statement of Objections on Teva's abusive practices

The Commission preliminarily finds that Teva abused its dominant position in the markets for glatiramer acetate in Belgium, Czechia, Germany, Italy, the Netherlands, Poland and Spain.

The Commission is concerned that Teva engaged in two types of abusive conduct, with an overall objective of artificially prolonging the exclusivity of Copaxone by hindering the market entry and uptake of competing glatiramer acetate medicines.

In particular, the Commission preliminarily found that since February 2015 until today Teva:

- **Misused patent procedures:** after the original, basic patent expired, Teva artificially extended glatiramer acetate's basic patent protection by filing and withdrawing secondary patent applications, thereby forcing its competitors to file new lengthy legal challenges each time. This scheme is sometimes referred to as the “divisionals game”. This is because the strategy implies filing so-called “divisional patents” which are patents derived from an earlier secondary patent and whose subject matter is already contained in the earlier patent. This artificially prolongs legal uncertainty to the benefit of the patent holder, and can effectively block or delay entry of generic or generic-like medicines.
- Implemented a systematic **disparagement campaign** targeting healthcare professionals and casting doubts about the safety and efficacy of a competing glatiramer acetate medicine and its therapeutic equivalence with Copaxone.

If the Commission's preliminary views were confirmed, Teva's behaviour would infringe Article 102 of the Treaty on the Functioning of the European Union ('TFEU'), which prohibits the abuse of a dominant position. If confirmed, Teva's behaviour would not only harm competitors and patients, but also inflate public health spending on certain multiple sclerosis treatments, which for Copaxone alone amounts to up to €500 million per year in the EU.

The sending of a Statement of Objections does not prejudge the outcome of the investigation.

Background

The Commission carried out unannounced inspections at the premises of several Teva subsidiaries in October 2019. On 4 March 2021, the Commission initiated proceedings against Teva Pharmaceutical Industries Limited and Teva Pharmaceuticals Europe BV.

The Commission regularly receives complaints about misuse of patents as well as about disparagement campaigns. On 20 June 2022, the Commission opened a formal investigation into possible anticompetitive disparagement by Vifor Pharma.

Article 102 of the TFEU prohibits the abuse of a dominant position. The implementation of these provisions is defined in the Antitrust Regulation (Council Regulation No 1/2003), which can also be applied by the national competition authorities.

A Statement of Objections is a formal step in Commission investigations into suspected violations of EU antitrust rules. The Commission informs the parties concerned in writing of the objections raised against them. The companies can then examine the documents on the Commission's investigation file, reply in writing and request an oral hearing to present their comments on the case before representatives of the Commission and national competition authorities.

If the Commission concludes, after the company has exercised its rights of defence, that there is sufficient evidence of an infringement, it can adopt a decision prohibiting the conduct and imposing a

fine of up to 10% of the company's annual worldwide turnover.

There is no legal deadline for the Commission to complete antitrust inquiries into anticompetitive conduct. The duration of an antitrust investigation depends on a number of factors, including the complexity of the case, the extent to which the companies concerned cooperate with the Commission and the exercise of the rights of defence.

More information on this investigation will be available on the Commission's competition website, in the public case register under the case number AT.40588.

Related topics

Competition Antitrust

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Antitrust: Commission sends Statement of Objections to Teva

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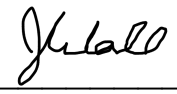
Exhibit “S7”

This is Exhibit “S7” referred to in the Affidavit of Emily Seaby, sworn before me this 26th day of July, 2024.



A Commissioner for Taking Affidavits, etc.
Jon Wall

HOUSE OF COMMONS
CANADA

A Plan to Modernize Canada's Competition Regime

Report of the Standing Committee on Industry, Science and Technology

Walt Lastewka, M.P.
Chair

April 2002

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A Plan to Modernize Canada's Competition Regime

Report of the Standing Committee on Industry, Science and Technology

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THE STANDING COMMITTEE ON INDUSTRY, SCIENCE AND TECHNOLOGY

has the honour to present its

EIGHTH REPORT

Pursuant to Standing Order 108(2), the Committee proceeded to a study of Canada's competition policy and framework, including the *Competition Act*. After hearing evidence, the Committee agreed to report to the House as follows:

TABLE OF CONTENTS

CHAIR'S FOREWORD

In June 2000, the House of Commons Standing Committee on Industry, as the current Committee was then known, produced an *Interim Report on the Competition Act*. This report followed an independent review of the anticompetitive pricing provisions of the *Competition Act* and the Competition Bureau's enforcement record, as was requested by the Bureau at the insistence of The Honourable John Manley, Minister of Industry. Professors J. Anthony VanDuzer and Gilles Paquet, both of the University of Ottawa, conducted this in-depth study dealing with predatory pricing, price discrimination and price maintenance. Their work, entitled *Anticompetitive Pricing Practices and the Competition Act: Theory, Law and Practice*, and subsequently known as the VanDuzer Report, was completed and presented to the Committee in October 1999.

After receiving this report and while the Committee was conducting its hearings process, the Bureau engaged the Public Policy Forum (PPF) — a non-profit, non-partisan organization dedicated to improving the quality of government in Canada — to consult the Canadian public widely on changes to the *Competition Act* and the *Competition Tribunal Act*. The changes contemplated in its consultations were those proposed in four Private Member's bills: Bill C-402, Bill C-438, Bill C-471 and Bill C-472. Two of these bills covered much the same policy ground as the Committee's study. Because the Committee did not want to prejudice this consultative process, it decided not to provide an opinion on any of the specifics of these bills and to make its report an interim one. The Committee would weigh in on these matters only after these consultations were complete and a report issued.

In December 2000, the PPF published its report, entitled *Amendments to the Competition Act and the Competition Tribunal Act: A Report on Consultations*, which summarized both the written submissions it had received and the discussions at the roundtables it had held. The Government of Canada then decided to wrap some of the contents of the four Private Member's bills into a government bill. The government chose the parts where a consensus could be obtained, including selected inputs from both this Committee's *Interim Report* and the PPF's report. All these efforts culminated in Bill C-23: *An Act to Amend the Competition Act and the Competition Tribunal Act*, which was assigned to this Committee for study after First Reading in the House of Commons. This course of action, rather than the traditional procedure of assigning the bill to a parliamentary committee only after Second Reading, permitted a more thorough review of the bill and the Acts that it sought to modify. This procedural route also allowed the Committee to study more deeply the changes contemplated and, if necessary, to recommend additional changes.

The bill dealt with four issues: (1) creating a new offence for "deceptive prize notices," including "scratch and win cards"; (2) facilitating cooperation with foreign competition authorities for the enforcement of civil competition and fair trade practices laws; (3) streamlining the administrative processes of the Competition Tribunal by

providing for cost awards, summary dispositions and references; and (4) broadening the scope under which the Tribunal may issue temporary orders. After extensive consultation with competition law experts and selected business interests, the Committee subsequently amended the bill in two important ways. The bill, if it receives Royal Assent as amended, will permit private parties to have access to the Tribunal for resolving disputes on a limited number of business practices that are considered civilly reviewable by the Acts. The Tribunal will also now be able to impose an administrative penalty of as much as $15 million if an air carrier is found guilty of abuse of dominance (sections 78 and 79 of the *Competition Act*, which would include acts of predatory behaviour).

The Committee believes that Bill C-23 amendments to the two competition Acts provide a good start, but more amendments are needed to address contemporary antitrust concerns. In some cases, the *Competition Act* captures too many business practices, which leads to a "chilling effect" on perfectly legitimate, pro-competitive behaviour on the part of Canada's most productive firms. At the same time, and in other cases, both competition Acts fail to capture and properly address many business practices that at least appear to be anticompetitive and may even constitute egregious anti-social behaviour. Therefore, more change is necessary, and the Committee agrees with the government's multi-stage approach to reform. Looking beyond the immediate horizon, the Committee undertook four roundtables that included more than 20 eminent competition law experts, as well as formal and informal meetings with the Bureau and members of the Tribunal, respectively, to suggest options and a timetable for reform.

Although interesting and varied opinions exist amongst competition policy experts on a number of business practices and their current legal status, as well as the way in which they should be reviewed and pursued by the Bureau and Tribunal, these views were not so diverse as to prevent a consensus. The Committee believes this consensus is captured in this report. However, the first-time reader of this Committee's reports is encouraged to read our *Interim Report* before tackling this one; a better understanding and appreciation will be gained on the necessary trade-offs in objectives presented by competition issues.

At this time, I would like to thank those who participated in our extensive hearings process and who shared their insights with us. I am confident that the public will agree that this report reflects both their concerns and common Canadian values and priorities in the domain of competition policy, law and enforcement. Finally, on behalf of the whole Committee, I wish to express our appreciation for the dedicated efforts of Ms. Susan Whelan, the former Chair of the Committee, and to acknowledge her important role in the creation of this report.

PREFACE

Competition legislation, or antitrust legislation as it is sometimes called, has existed in Canada for more than 100 years. While the name or title of the governing Act has changed several times over the years,[1] each revision has refined it and made it a more effective instrument of the public interest. These revisions were necessary to fill major breaches in the Act because serious limitations in its enforceability became obvious almost immediately from the law's earliest contested cases. Canada was the first industrial country out of the gate to adopt an antitrust law in 1889 but, from a practical sense, Canada fell well behind most major industrialized nations fairly early on in the realm of competition matters. In the intervening years between the original Act of 1889 and the current Act of 1986, Canada's competition law could hardly have been touted as being on the vanguard of competition policy; much more work had to be done, and on a limited number of important issues still remains to be done, to realize such a lofty status.

The primary goal of the legislation — from the first to the latest — remains the same: the quashing of conspiracies and monopoly-making restraints of trade (except those created by federal and provincial legislation). The Committee's *Interim Report on the Competition Act* (hereinafter the "*Interim Report*") provides some limited chronology of the revisions taken to date. In this report, the Committee wants to limit the amount of rehashing of this history. Our point of departure will be the adoption of the *Competition Act* and the *Competition Tribunal Act* in 1986; in the interest of brevity, we will revisit only the most significant amendments to these Acts and the economic conditions that spawned them.

At the outset, the Committee observes five relatively recent economic trends that are becoming pervasive in today's society — trends that, in all probability, cannot be divorced from the knowledge-based economy that we are building. These economic phenomena include: (1) a shift in corporate strategies that seek a competitive advantage through the attainment of economies of scale and scope and towards innovation; (2) the organizational drive to delayer many large corporate hierarchies through spinning off non-core activities to separate businesses and the forging of strategic allies or, alternatively put, the development of business networks in the hopes of raising productivity; (3) the adoption of new technologies, particularly digital technologies, that require substantial up-front investments with low or next-to-zero incremental unit costs that may lead to very aggressive pricing policies in economic downturns; (4) the adoption of products, most notably software programs such as Microsoft Windows, that may eventually develop into an industry standard, which will often be accompanied by network

[1] The original Act was called *An Act for the Prevention and Suppression of Combinations Formed in Restraint of Trade* in 1889, which was repealed and replaced by the *Anti-Combines Act* of 1915. This new Act was repealed and replaced by two Acts: the *Board of Commerce Act* and the *Combines and Fair Price Act* in 1919, which were later ruled *ultra vires*. These Acts were then replaced by the *Combines Investigation Act* of 1923, which was in turn repealed, thoroughly reworked and replaced by the *Competition Act* of 1986.

effects[2] and may consequently lead to unusually high levels of market concentration (including near-monopolization); and (5) the internationalization of commerce — trade and investment — in the wake of new transportation and communications technologies, with their attendant lower costs, and government policy favouring the removal of significant tariff barriers to trade around the globe. Each of these new developments has been a catalyst for changes to the *Competition Act* and the *Competition Tribunal Act*.

These economic phenomena and the competition concerns that they raise can be seen as the main causes of a flurry of government and Private Member's bills that have made it to the *Order Paper* of the House of Commons. Indeed, one of the best barometers a democratic country has for measuring the public's dissatisfaction with what is going on in the marketplace may be found in the number of bills or amendments for change. In the case of amendments to the *Competition Act* and the *Competition Tribunal Act*, nine Private Member's bills and two government-sponsored bills (Bill C-26 of the 36th Parliament and Bill C-23 of 37th Parliament) have arisen in the last two years alone.

The Committee suggests that the almost simultaneous appearance of these bills and the above-cited economic trends are no accident; there is a causal relationship flowing from economic trend to *Competition Act* amendment. For example, the local telephone network is the perennial case of a "network economy or externality." Cable television, rail freight services, electrical power and natural gas distribution also belong to this special industrial species, as is the recently deregulated airline industry. Some of the technologies used by airline companies also display very low incremental unit costs relative to total costs. The traditional way of handling these cases of near or "natural monopoly" has been to regulate them. Since the late 1980s, however, airline, rail freight, long distance telephone and international telecommunications services have been partially deregulated because technology developments suggest that they no longer harbour the natural monopoly characteristic. Only the deregulation of the airline industry has proven controversial. Here, the relatively small Canadian market and the federal government's maintenance of foreign ownership restrictions on the operation of air carrier services have conspired to produce a highly concentrated market, frustrating both the travelling public and would-be start-ups in the industry. Bill C-26, an amendment passed in the 36th Parliament in 2000, was an attempt to address this problem subsequent to the imminent failure of Canadian Airlines International Inc. and its merger with Air Canada Inc. The failure of many smaller airline companies in the past few years (Royal Airlines, Greyhound Airlines, Canjet, Canada 3000) and the sheer dominance of Air Canada in the Canadian market were the stimulus for an amendment to Bill C-23. This amendment would give the Competition Tribunal the power to assess an administrative penalty of as much as $15 million if an air carrier is found guilty of abuse of dominance. As such, the

[2] A "network effect," or as it is sometimes called a "network economy," refers to an enhanced value an individual already subscribing to a business network would assign to the service with the addition of more customers. Using the local telephone network as an example, the larger the number of telephone subscribers to the local network, the greater the willingness to pay for service on the part of each subscriber. Such a "network economy" is also often referred to as a "network externality" because it is a value that is external to the firm but internal to the industry. Regulatory agencies across the world have been notorious in capturing and exploiting this externality through mandatory and implicit cross-subsidy pricing regulations.

government is departing from the traditional approach of arming the industry's regulator with the necessary powers to directly control these aspects of competitive behaviour. The government has instead taken a "special rules for special industries" approach, which calls into question the claim that the *Competition Act* is framework legislation, justifying it on the grounds that this industry comes under federal regulatory jurisdiction.

Bill C-23 addresses the increasing internationalization of commerce in two important ways. First, this bill would facilitate cooperation between the Competition Bureau and foreign competition authorities for the enforcement of civil competition matters now that monopolization practices can transcend country boundaries. Second, the Committee amended this bill to give private parties access to the Competition Tribunal for resolving disputes on a limited number of business practices that are considered civilly reviewable by the Acts. This amendment should comfort many small- and medium-sized businesses that may have to combat large multinational enterprises which attempt to abuse their dominant position.

Finally, increased innovation across most sectors of the economy demands quicker resolution of disagreements between private parties and the Bureau on controversial competition issues. Bill C-23 responds to such demands by proposing to streamline the Tribunal's administrative processes through the provision of cost awards, summary dispositions and references.

Bill C-23 will provide a good first step to strengthening the *Competition Act*. More steps, however, must be taken. Industry and competition experts complain that the law is over-inclusive in some areas of antitrust, but under-inclusive in other areas. The typical example of over-inclusiveness has been the law's inability to properly distinguish between a strategic alliance and a conspiracy to raise prices to the detriment of the public, which has a "chilling" effect on some profitable and competitively benign opportunities that the business sector would otherwise undertake (despite the development of the Bureau's bulletin: *Strategic Alliances Under the Competition Act*). Conventional thinking suggests that a strategic alliance is preferred to a full-blown merger as a means of gaining cooperative behaviour between rival companies with distinct core competencies. The perennial example of the law's under-inclusiveness is found in the term "unduly" in section 45 of the Act — again dealing with a conspiracy — which makes it hard to obtain a conviction in a contested case; this is true even when the case is, for all intents and purposes, a "naked hard-core cartel" with no redeeming social value.

Furthermore, a growing number of stakeholders believe that the *Criminal Code* is not well suited to distinguish between anticompetitive conduct and perfectly legitimate pro-competitive conduct when it comes to price discrimination, predatory pricing and vertical price maintenance practices. Shifting these pricing provisions over to the civilly reviewable side of the Act deserves further consideration. Competition Bureau resource issues, including the thresholds for merger review, are also a cause for concern and so are the processes and powers of the Competition Tribunal. Resolution of these issues is the task of this report.

LIST OF RECOMMENDATIONS

1. **That the Competition Bureau designate conspiracies as one of its highest priorities and that it allocate enforcement resources consistent with this ranking. That the Competition Bureau continue implementing existing enforcement strategies that target domestic and international conspiracies against the public, independently and jointly with competition authorities of other jurisdictions. As a matter of routine, that the Competition Bureau review its tactics of crime detection with a view to improving its existing record of success.**

2. **That the Competition Bureau review its enforcement guidelines, policies and practices to ensure appropriate emphasis is placed on dynamic efficiency considerations in light of new challenges posed by the knowledge-based economy, including factors such as: (1) high rates of innovation; (2) declining or zero marginal costs on additional units of output; (3) the possible desirability of market dominance by a firm where it sets a new industry standard; and (4) the increasing fragility of dominance.**

3. **That the Government of Canada empower the Competition Tribunal with the right to impose administrative penalties on anyone found in breach of sections 75, 76, 77, 79 and 81 of the *Competition Act*. Such a penalty would be set at the discretion of the Competition Tribunal.**

4. **That the Government of Canada repeal all provisions in the *Competition Act* that deal specifically with the airline industry (subsections 79(3.1) through 79(3.3) and sections 79.1 and 104.1).**

5. **That the Government of Canada provide the Competition Bureau with the resources necessary to ensure the effective enforcement of the *Competition Act*.**

6. **That the Competition Tribunal develop and articulate a policy to allocate costs in a fair and equitable manner having regard to the resources available to the parties to the proceeding. That such a policy consider the merits of exempting small businesses from liability for costs in Tribunal proceedings.**

7. **That the Competition Tribunal, in consultation with the Tribunal-Bar Liaison Committee, continue its ongoing review of procedures with the aim of creating an adjudicative system that**

will ensure "just results" in an expeditious and timely manner. Such procedures should aim at reducing parties' costs, as well as the time required, in bringing contested cases to a conclusion while, at the same time, continuing to ensure that due consideration is given to principles of procedural fairness and the appearance of justice.

8. **That the Government of Canada amend the *Competition Act* and the *Competition Tribunal Act* to extend the private right of action in the case of abuse of dominant position (section 79) and to permit the Competition Tribunal to award damages in private action proceedings (sections 75, 77 and 79).**

9. **That the Government of Canada amend section 124.2 of the *Competition Act* to permit a party to a contested proceeding under Part VII.1 or VIII to refer to the Tribunal a question of law, jurisdiction, practice or procedure in relation to the application or interpretation of Part VII.1 or VIII.**

10. **That the Government of Canada amend section 12 of the *Competition Tribunal Act* to permit questions of law to be considered by all the members sitting in a proceeding.**

11. **That the Government of Canada amend section 13 of the *Competition Tribunal Act* to require that an appeal from any order or decision of the Tribunal may only be brought with leave of the Federal Court of Appeal.**

12. **That the Government of Canada amend the *Competition Act* to create a two-track approach for agreements between competitors. The first track would retain the conspiracy provision (section 45) for agreements that are strictly devised to restrict competition directly through raising prices or indirectly through output restrictions or market sharing, such as customer or territorial assignments, as well as both group customer or supplier boycotts. The second track would deal with any other type of agreement between competitors in which restrictions on competition are ancillary to the agreement's main or broader purpose.**

13. **That the Government of Canada repeal the term "unduly" from the conspiracy provision (section 45) of the *Competition Act*.**

14. **That the Government of Canada amend the *Competition Act* by adding paragraphs to section 45 that would provide for exceptions based on factors such as: (1) the restraint is part of a**

broader agreement that is likely to generate efficiencies or foster innovation; and (2) the restraint is reasonably necessary to achieve these efficiencies or cultivate innovation. The onus of proof, based on the "beyond a reasonable doubt" standard, for such an exception would be placed on the proponents of the agreement.

15. That the Government of Canada amend the *Competition Act* to add a paragraph to section 45 that would prohibit any proceedings under subsection 45(1) against any person who is subject to an order sought under any of the relevant reviewable sections of the *Competition Act* covering essentially the same conduct.

16. That the Government of Canada amend the civilly reviewable section of the *Competition Act* to add a new strategic alliance section for the review of a horizontal agreement between competitors. Such a section should, as much as possible, afford the same treatment as the merger review provisions (sections 92 through 96), and should authorize the Commissioner of Competition to apply to the Competition Tribunal with respect to such agreements that have or are likely to have the effect of "preventing or lessening competition substantially" in a market.

17. That the Government of Canada ensure that its newly proposed civilly reviewable section dealing with strategic alliances, as found in recommendation 16, apply to agreements between competing buyers and sellers, but not to vertical agreements such as those subject to review under sections 61 and 77 of the *Competition Act*.

18. That the Competition Bureau establish, publish and disseminate enforcement guidelines on conspiracies, strategic alliances and other horizontal agreements between competitors that are consistent with recommendations 12 through 17 that would amend the *Competition Act*.

19. That the Government of Canada amend the *Competition Act* to allow for a voluntary pre-clearance system that would screen out competitively benign or pro-competitive horizontal agreements between competitors from criminal liability pursuant to subsection 45(1) of the Act. That the Competition Bureau levy a fee on application for a pre-clearance certificate that would be based on cost-recovery principles similar to that of a merger review. That a reasonable time limit upon application for a certificate be imposed on the Commissioner of Competition,

failing which the applicant is deemed to have been granted a certificate.

20. That the Government of Canada amend the *Competition Act* to allow individuals who have been refused a pre-clearance certificate for a horizontal agreement between competitors by the Commissioner of Competition be given standing before the Competition Tribunal for a fair hearing on the proposed agreement. That such standing be granted only if the agreement remains proposed and has not been completed.

21. That the Government of Canada repeal paragraphs 50(1)(*b*) and 50(1)(*c*) of the *Competition Act* and amend the Act to include predatory pricing as an anticompetitive act within the abuse of dominant position provision (section 79).

22. That the Government of Canada repeal the price maintenance provision (section 61) of the *Competition Act*. In order to distinguish between those practices that are anticompetitive and those that are competitively benign or pro-competitive, that the Government of Canada amend the *Competition Act* so that: (1) price maintenance practices among competitors (i.e., horizontal price maintenance), whether manufacturers or distributors, be added to the conspiracy provision (section 45); and (2) price maintenance agreements between a manufacturer and its distributors (i.e., vertical price maintenance) be reviewed under the abuse of dominant position provision (section 79).

23. That the Government of Canada repeal the price discrimination provisions (paragraph 50(1)(*a*) and section 51) of the *Competition Act* and include these prohibitions under the abuse of dominant position provision (section 79). This prohibition should govern all types of products, including articles and services, and all types of transactions, not just sales.

24. That the Government of Canada amend the *Competition Act* by deleting paragraph 79(1)(*a*).

25. That the Competition Bureau revise its *Enforcement Guidelines on the Abuse of Dominance Provisions* in order to be consistent with the addition of the anticompetitive pricing practices (paragraphs 50(1)(*a*) and 50(1)(*c*) and section 61) to section 79 of the *Competition Act*.

26. That the Government of Canada amend section 110 of the *Competition Act* to require parties to any merger (i.e., asset or

share acquisitions) involving gross revenues from sales of $50 million in or from Canada to notify the Commissioner of Competition of the transaction.

27. **That the Government of Canada amend the *Competition Act* to have a parliamentary review of the notification thresholds contained in sections 109 and 110 within five years and every five years thereafter to ensure optimal enforcement of the *Competition Act*.**

28. **That the Government of Canada immediately establish an independent task force of experts to study the role that efficiencies should play in all civilly reviewable sections of the *Competition Act,* and that the report of the task force be submitted to a parliamentary committee for further study within six months of the tabling of this report.**

29. **That the Competition Bureau issue an interpretation guideline clarifying whether section 75 would apply to the circumstance where a supplier in a market characterized by supply shortages could selectively ration its available supply in such a manner as to discriminate against independent retailers.**

INTRODUCTION

Canada's original competition law was born out of the public's dislike for some of the business combinations that were being formed just prior to the turn of the 20th century. However, as history would later show, the large-scale businesses that were fashioned from key mergers and acquisitions in related activities at that time were, for the most part, an organizational response to innovation in products and processes that resulted in vast economies of scale. These scale economies dictated new business strategies based on massive investments in physical capital as well as a commitment to building integrated operations extending backward into core raw materials and forward into marketing and distribution networks. Furthermore, these strategies could only just then be implemented with the opening up of more distant markets as integrated railway and telegraph networks were developed.

I … encourage the Committee to rise to the challenge and provide a more ambitious blueprint for the modernization of our Act … It's my hope that this blueprint will form the basis of a government white paper that will … launch the next round of amendments. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:11:15]

Unfortunately, this good came with the bad. The unprecedented cost advantages bestowed upon large-scale operators led to the elimination of many small-scale merchants. So the world's first antitrust law — Canada's *An Act for the Prevention and Suppression of Combinations Formed in Restraint of Trade* — was enacted in an attempt to assure the public on two grounds: first, this industrial transformation would occur in an orderly way, only the inefficient would be driven out of business and not efficient small-scale operators through predatory means; and second, in the end, the ultimate beneficiaries of technological and organizational change would be consumers. The original antitrust legislation, as well as the three Acts that would replace it, had three targets: conspiracies to raise prices; mergers and acquisitions that would monopolize markets; and a dominant firm's abusive business practices and predator policies that would injure, rein in or drive out its smaller rivals.

[Y]ou … need amendments … to make the Act more effective in addressing anti-competitive conduct and … to reduce the chilling effect the Act … has on a broad range of pro-competitive conduct, whether it's these pricing practices …, or horizontal cooperation, which … in the vast majority of circumstances is pro-competitive once you get outside this limited category of hard-core criminal cartel conduct. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:12:45]

The modern version of the original antitrust Act, now known as the *Competition Act*, is a well-crafted economic instrument designed to preserve and enhance the process of competition. It is a law of general application; it applies to

I think the proposals for the two tracks, criminal versus civil in section 45, is something that will have to be done … it's the sensible thing to do. [Jeffrey Church, University of Calgary, 59:10:55]

all industries in equal measure (except those provided an exemption by federal or provincial legislation) and puts the interest of no one competitor or class of competitor ahead of those of any other. Canada's *Competition Act*, the Competition Bureau and the Competition Tribunal have supplemented the competitive process in producing an economic environment in which non-compliance with the law is more the exception than the rule. This has been accomplished by:

- establishing a broad competition framework, thereby setting "the rules of the game";
- making the guidelines of the enforcement agency — the Competition Bureau — widely available to the business community;
- having the Bureau fulfil its advocacy role at many regulatory hearings and other public events, thereby making the rules known to all players; and
- judiciously enforcing the many provisions of the Act under the watchful eye of the referee — the Competition Tribunal — so that the game is called according to the rules.

The difficulty with the reform of section 45 is not … that there's any disagreement around the evil of hard-core cartels. The difficulty is whether you can … write … a law that is not massively over-inclusive. [Neil Campbell, McMillan Binch, 59:12:55]

At the turn of the 21st century, a similar set of circumstances to that of the turn of the 20th century appears to be unfolding. The source of change is again innovation, but this time it has less to do with cost advantages of scale and scope associated with new physical capital and more to do with creative advantages associated with "human capital." Rather than exploiting the size and scope of a firm, or more succinctly, the efficiencies obtained through central direction of an industrial hierarchy, the business corporation is focusing on being lean and nimble. Many modern corporations are, therefore, spinning off non-core competency activities, while weaving ever-larger webs of business networks. This organizational structure — which relies on independent, highly specialized, interdisciplinary work teams — provides focus to the firm at a time when the currency of the so-called "Information Age" is the creative talents of the workforce. The business sector is thus banking on increased productivity through a strategy of creative competitive advantage. When one combines these corporate developments with innovations (such as containerization in transportation and digitalized broadband in wired and wireless telecommunications) and policy shifts

[W]hy do we not have a Microsoft case in Canada? Seventeen states in the U.S., the federal government in the U.S., and Europe have all looked at that. There's no argument that the impact in Canada … is any different. … [T]he answer: We don't have the funding to take that abuse case in Canada. [Robert Russell, Borden, Ladner & Gervais, 59:09:50]

to more liberalized trade and deregulated industries, the business landscape is increasingly becoming global rather than national.

My own reading of what the Bureau has … in the merger area is that … they are probably pretty well funded … The user fees have provided a cashflow to assist in that. [Neil Campbell, McMillan Binch, 59:12:35]

Firms using today's newest business models, such as "just-in-time" production and "Big Box" retailing, are exerting tremendous pressure on small and medium-sized businesses that are not adjusting. As a result, new stresses and fracture points in the competition policy framework are appearing once again. Although the *Competition Act* is a modern piece of legislation that reflects contemporary economic thinking and provides a balanced approach to enforcement, there are signs that it can be made more effective in certain areas and, where it is already effective, can be made more efficient. Amendments to selected provisions of the *Competition Act* and to the administrative processes of the Competition Tribunal are the order of the day.

The Committee began answering the call for a modern and effective competition law regime in its *Interim Report*. We broached, amongst other issues, the private right of action in respect of some civilly reviewable matters, such as refusal to deal (section 75), exclusive dealing, tied selling, and market restriction (section 77) and delivered pricing (section 80). With the Public Policy Forum's subsequent finding of a favourable consensus (provided that adequate safeguards against vexatious and frivolous suits were put in place), the Committee amended Bill C-23 in favour of such rights (excluding section 80). Consequential amendments were also necessary. The Committee further amended section 75 to ensure that an "adverse effects on competition" test was added, which would eliminate any incentive for frivolous commercial disputes, given that the Commissioner would no longer be the gatekeeper of these sections.[1]

In terms of … enforcement … there are really three things that can be dealt with … There is this question of funding … the question of alternative enforcement mechanisms like private access, which … for civil cases would help the Bureau a great deal by taking some of the workload away from them. The other area on the agenda … is … reform of the Tribunal process. [Margaret Sanderson, Charles River Associates, 59:11:20]

[1] Typically, the "competitive effects test" used in the Act is that of a "substantial lessening of competition." Section 75 will, however, use an "adverse effects on competition" test. The meaning of "substantial lessening of competition" has been refined to a degree by judicial interpretation and the meaning of "adverse effect on competition" will have to be similarly clarified. The use of the "adverse effects" test in section 75 is to permit small and medium-sized enterprises the opportunity to have their cases heard in the new private access regime. In the case of a firm with a small market share, a refusal to deal might not "substantially lessen" but still "adversely affect" competition. The requirement to show a "substantial lessening of competition" in a market would be likely to exclude private action in all but the largest cases.

The Committee's actions will not stop there; we intend this report to become a blueprint for a government White Paper that will launch the next round of amendments to the *Competition Act* and the *Competition Tribunal Act*. The report will identify both the relevant sections of the two Acts needing reform and the pertinent issues related to the options under consideration. Once these options for reform are clarified, the Committee will weigh them, look for consensus amongst the various stakeholders, and recommend a course of action; where warranted, a timetable for reform may also be provided. The reasoning for the Committee's preferences will be spelled out in detail where possible, as the Committee finds transparency an essential ingredient to the reform of complex issues involving competition policy and its many varied stakeholders.

[T]here's been a tendency to describe private action as … a … way of helping the Commissioner out, … putting more resources into his pocket and doing some of his work … but I don't see it that way … [O]ne has to think much more broadly about private action … [as] a way of … enlarging the scope of competition cases. … [W]e should get a much richer case law and a much richer body of decisions from which to draw. [Roger Ware, Queen's University, 59:11:35]

Although the Committee is not under the illusion that only one combination of reforms is possible or desirable, we do caution both the reader and policy-maker that the recommendations offered here are a package of reforms that are not easily cherry-picked due to the *Competition Act*'s complex set of interrelationships within its different sections. Attempts to select among these recommendations to craft a different competition framework or different strategy are not without consequences.

[T]here's a theme percolating that jurisprudence is just inherently good and we should have lots of it. I'm concerned about that, because it's a very costly way to create law, relative to legislation that's fleshed out by regulations or guidelines, which have their imperfections but can also play a much more efficient and faster role in many areas. The real question … is how do we ensure that we get good, economically sound competition law enforcement …? [Neil Campbell, McMillan Binch, 59:12:15]

The plan of this report is as follows. In Chapter 1, the Committee picks up the discussion on the historical background of competition law and policy and the key economic developments that are challenging Canada's competition framework today, as set out in this introduction, by placing it in three settings. We first venture into the proper role of competition law given our understanding of the workings of the process of competition and the impacts of other complementary government policies. Gaining an appreciation for the interplay of these influential factors, we are able to establish a suitable role for competition law in Canada. In the second setting, a comparative analysis of different competition law provisions, involving both criminal and civil matters, is undertaken; this analysis suggests an optimal enforcement strategy for a mid-sized, open-trading economy — the Canadian circumstance. Finally, the merits of framework law versus "special provisions for special

industries" approach are debated, concluding in favour of a return to a framework law, but one that is bolstered by more general enforcement powers than in the past.

In Chapter 2, the Committee reports on the state of competition in Canada and the state of enforcement. In analyzing the latter's contribution to the former, we distinguish between the Bureau's array of enforcement instruments, enforcement guidelines and resources, and its Commissioner's independence and accountability structure. We also evaluate the role of the Tribunal and the courts, the deterrence incentive structure of fines and jail time, as well as the enforcement potential that private rights of action are likely to provide. In Chapter 3, the Committee discusses the role of the Competition Tribunal and its decision-making procedures.

Innovation is a lot faster. Transactions are taking place in nanoseconds, as opposed to quill pens on parchment. The pace of market behaviour is so fast today that it really imposes a very difficult challenge on an enforcement agency. [George Addy, Osler, Hoskin & Harcourt, 59:12:00]

In chapters 4, 5, 6 and 7, the Committee addresses the important provisions of the *Competition Act*: conspiracy; the anticompetitive pricing practices; acts constituting abuse of dominance; and merger review. In each chapter, we assess the economic content of the law, the merits and appropriateness of whether the relevant practices should be placed in the criminal or civil part of the Act, the substantive elements of each provision and the Bureau's administration. The contentious issues will be identified, sorted out and thoroughly assessed in light of modern economic exigencies. The Committee will advance reforms where a consensus can be reached; where it cannot, further study is recommended.

[I]t would be very helpful if your final report provided a strong endorsement of the principle that competition law as framework legislation ought not to be expanded to include a hodgepodge of industry-specific amendments. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:11:15]

In Chapter 8, the Committee considers a narrow but important issue dealing with the application of the refusal to deal provision (section 75) in gasoline retailing. That industry presents particular competition concerns because independent retailers must necessarily depend on large, vertically integrated producers who both supply and compete with them. Could a large, vertically integrated producer restrict competition by withholding supply to a competing independent retailer in the case of a general supply shortage? And, if so, how would the *Competition Act* respond? Answers to these questions are necessary because there may be competition implications for other

sectors of the Canadian economy where vertical integration is also a structural characteristic. Finally, in the Conclusion, the Committee summarizes its recommendations for improvement of the competition policy framework.

CHAPTER 1: CANADA'S COMPETITION REGIME IN CONTEXT

Competition and Competition Policy Interplay

The interplay between the process of competition and competition policy and law is an interesting one. Competition is a means to an end, not an end in itself. We have competition so the business sector can deliver the best combination of products at the best prices to consumers. The best deal a consumer can receive comes from a free and open market, one with as few barriers to entry by new competitors and as few exit barriers,[2] including government-imposed barriers such as product, investment or trade regulations.[3] Indeed, certain government policies other than competition policy deliberately or inadvertently restrict competition, and competition policy (although sometimes controversial) is required to restore some sort of balance. However, even in the absence of government-imposed barriers, unfettered competition alone may not be enough. A complementary competition law is required in circumstances where, owing to technological barriers, competition will not automatically and immediately flourish.

[T]here's a need for something to be said about competition policy being broader than simply the competition law. There's a need to extend our competition policy to address the broader range of federal, provincial, and municipal government restraints to competition. In aggregate, these have a far greater adverse impact on consumers, small businesses, and large businesses in Canada than all private restraints combined. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:11:20]

I think the theme or principle behind the Competition Act*, which is that competition as a process is going to generate tremendous benefits, is a valid one that applies across industry segments.* [Tim Kennish, Osler, Hoskin & Harcourt, 59:09:55]

This interdependence of the process of competition and competition policy also runs in the opposite direction when governments adopt policies that, deliberately or inadvertently, foster competition. For example, trade liberalization provided by the Canada-United States Free Trade Agreement (FTA), followed by the North American Free Trade Agreement (NAFTA), was not only good trade policy, but also good competition policy. The deregulation and privatization of key industrial sectors of the economy,

[T]he Competition Act *is intended to and should protect the competitive process, and it is intended to ensure market conditions where a good company … can survive and do well … it should not be protecting any individual company.* [Donald McFetridge, Carleton University, 59:10:00]

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2 This last condition is particularly relevant in recent years to the retail sector with the move to the "Big Box" sales format, and, in particular, gasoline retailing given the exit barriers presented by environmental laws governing the decommissioning of underground gas tanks.

3 Government policies — such as CRTC telecom and cable and satellite television regulations, the dairy and poultry quota systems, airline ownership and cabotage services restrictions, Ontario's beer and liquor distribution system, first-class postal mail and interprovincial trade restrictions — represent a number of such barriers.

[A]n open international trade policy is in many ways a better way of creating competition than through a legal enforcement of one's own competition laws and, I should add, open foreign investment policy. [Roger Ware, Queen's University, 59:13:05]

while proving controversial as an industrial policy, has in general been good competition policy.

There are at least two cases that have preoccupied the resources of the Competition Bureau and the Competition Tribunal in the last five years that might not have even been there had we had a more open, continent-wide approach to these industries. I'm referring, of course, to airlines and book retailing. [Roger Ware, Queen's University, 59:11:35]

Regulated markets, or deregulated markets where the proper institutions for fostering competitive entry are not put in place in the transition period, can also distort a competition policy regime. Indeed, twisting the competition law to accommodate an anticompetitive regulatory environment is likely to compromise and even corrupt competition law. In the 1980s, Canadians witnessed the intervention of their competition authorities in what otherwise might have been an efficiency-enhancing merger of dairies (*Palm Dairies Ltd*.) because of production quotas and interprovincial trade barriers that limited competition in the downstream sector. In the 1990s, Canadians again witnessed their competition authorities intervening in book retailing (the merger of SmithBooks and Coles Book Stores Ltd. in 1995 to form Chapters Inc. and in 2000 with the merger of Chapters and Indigo) because of entry barriers that were built by government-imposed ownership restrictions. Today, Canadians are witnessing the enactment of "special rules for a special industry" — the air carrier services industry — into a framework law, as a result of the absence of a suitable deregulatory framework.

In general, we have this problem that when we move from regulation to deregulation, the regulator is involved, and it takes an active role in making sure that the right policies are in place to facilitate competition. We haven't had that in airlines. I don't think you should be looking for the Commissioner to save Canadian consumers … You should be looking at … Transport Canada. [Jeffrey Church, University of Calgary, 59:10:30]

An Optimized Competition Framework

Any competition framework, if it is to improve consumer welfare and economic efficiency, must incorporate the most up-to-date economic analysis. There is, nevertheless, considerable room to manoeuvre in the choice of framework. Competition law usually reflects the country's culture, business customs, legal history, political philosophies, as well as its geographic size and demographic makeup.

The statute is still … an economically sophisticated law, and is recognized as such around the world. [Lawson Hunter, Stikeman Elliott, 59:10:50]

For example, the United States antitrust agency — the U.S. Federal Trade Commission — begins to get tough on mergers at much lower levels of industrial concentration than does Canada's Competition Bureau. This approach is taken because in the much larger

U.S. economy, there is much less risk that firms will not achieve the necessary economies of scale and scope to be efficient. Furthermore, Canada's competition legislation is unique in that it provides an efficiencies defence which explicitly requires that the review of a merger balance the anticompetitive effects against the "gains in efficiency." Whichever of the two impacts is greater determines the merger proposal's acceptability or unacceptability.[4] This provision appears to be more lenient than in the United States, where the efficiency gains must be so great that prices will not rise as a result of the merger. However, the Committee heard evidence to suggest that even Canada's consideration of efficiencies is not adequate.

I don't think the system is irreparably broken. I think it is a system we can continuously improve … We should be doing that on an ongoing basis. [George Addy, Osler, Hoskin & Harcourt, 59:12:55]

Although the much smaller Canadian economy dictates a less vigilant merger enforcement framework than exists in the United States, it could be argued that Canada ought to have a more vigilant conspiracy enforcement framework than the United States to achieve similar levels of enforcement. This view follows from two realities: Canada is a smaller market that is more susceptible to technological barriers to competition; and its economy is subject to more government-imposed regulatory barriers to competition. As such, leniencies found in Canada's merger review process can be made up elsewhere, for example, by having a more stringent provisions on: conspiracy, anticompetitive pricing practices, market restriction, tying and abuse of dominance. A careful balancing of factors is required to produce an optimal competition policy mix.

Certainly in 1986 we were able to hold up the Competition Act *at that time in a very proud manner and point to a number of aspects of the legislation that really did bring it to the attention of other jurisdictions. But one of the ongoing deficiencies continues to be section 45 … it is out of kilter in relation to hard-core, naked cartels. It's out of kilter with other jurisdictions …* [Calvin Goldman, Davies, Ward & Beck, 59:09:40]

Indeed, the needed balance can be a subtle one, particularly at the enforcement stage. For example, one witness appearing before the Committee in early 2000, a former Director of Investigation and Research at the Bureau of Competition Policy (as the title and the agency were known prior to the mid-1990s) said that not enough attention was paid to the significance of the consolidation going on in the refining sector in the oil industry in the 1980s. The Bureau allowed the consolidation to take place, and this development explains, in part, why we are today experiencing many problems in the downstream petroleum

[4] This interpretation has been put into doubt due to recent events, i.e., the Federal Court's ruling on appeal of the *Superior Propane* case.

products sector.[5] If this view is indeed correct, then the organizational structure of the oil industry may present an almost unsolvable competition problem, far too complex for the anticompetitive pricing provisions of the *Competition Act*. Yet, at the same time, the Committee recognizes that the government has and continues to work on improving this situation. In any event, this hypothesis, whether correct or not, confirms the importance of correctly crafting the competition framework — one that fits Canada's unique economic circumstances.

You could give the Bureau as many resources as you wanted, and that wouldn't address the basic point that it's very difficult to establish beyond a reasonable doubt that any competitive predatory pricing has occurred. It wouldn't address the point that if someone chose to contest a section 45 case — we're talking about hard-core criminal behaviour … [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:12:50]

According to many competition policy and law experts, the above problem is more widespread than is generally perceived. Some witnesses immediately pointed to the newspaper and grocery retailing industries as examples. Whether right or wrong, these comments suggest that Canada may indeed have a less-than-optimal competition enforcement strategy than what is required by a small, regulated or mixed economy.

When you're running an operation like that [Competition Bureau], you're constantly worried about two things. You're worried about … the "type one" errors, where you haven't taken enforcement action when you should have. You're also worried about the "type two" errors, where you have taken enforcement action in a benign case that may have caused narrow damage to those parties or a chilling effect on the marketplace. Dealing with those challenges in the environment we face in today's business climate is very, very difficult. [George Addy, Osler, Hoskin & Harcourt, 59:13:00]

Many competition law experts have three perennial criticisms of the *Competition Act*. First, Canada's conspiracy law, relative to other countries, is ineffective due principally to overly restrictive wording found in the provision (section 45). Consequently, the Commissioner of Competition has a poor record in contested conspiracy cases relative to the competition authorities in other jurisdictions. Second, Canada's conspiracy provision is both over-inclusive of some business arrangements in some circumstances and under-inclusive in others. In other words, the conspiracy provision is a very blunt instrument (see Chapter 4).

5 However, these events may themselves be inadvertent consequences of federal government regulations imposed on product formulas related to environmental emissions and export controls on crude petroleum in the 1980s that forced Canadian refiners to rely more heavily on the more costly heavy crude oil feedstock. The ensuing lower productivity levels may thus have meant that greater efficiencies through rationalization were needed to remain competitive with U.S. producers in what is a North American market for petroleum products.

Third, the Competition Bureau focuses its resources too heavily on merger review and too little on conspiracy enforcement.[6]

With respect to the second inference — the right mix of enforcement priorities — one would think that a small economy such as Canada would have a less vigilant merger enforcement regime than a large country such as the United States, relatively speaking and holding overall competition objectives the same, for the reasons already stated; and exactly the opposite situation in terms of conspiracy enforcement. Yet if the above complaints are true, Canada either has an inappropriate mix of competition law enforcement for its particular circumstance, or it is simply more lax on competition matters than are other major industrialized countries. This position further suggests that those who heralded the *Competition Act* as a watershed advancement over that of the *Combines Investigation Act* were much more critical of the predecessor Act than is commonly understood. In any event, consensus opinion appears to support that Canada moved from having a relatively ineffective competition statute prior to 1986, due principally to the higher burden of proof associated with the Act's criminal rather than civilly reviewable approach, to having one that, although more up to date in its economic content and legal treatment, is still somewhat misguided in a strategic sense. The Committee's report will, therefore, devote its efforts to correcting this defect. We will propose reform to the conspiracy provision that will make it more effective. Upon such change, we want the Bureau to aggressively pursue conspiracies against the public. The Committee, therefore, recommends:

[T]he Bureau's approach to merger review over-commits it in this area. If you examine statistical data, as compared with the U.S. experience with Hart-Scott, we're spending longer on cases, there are more cases, and they're getting extended reviews. This is absorbing a tremendous amount of time. I think we need to recognize that a very small proportion of them really do raise any significant issues. [Tim Kennish, Osler, Hoskin & Harcourt, 59:10:55]

I think a lot of the resource emphasis within the Bureau has been placed on merger review. Part of that is understandable. … From an enforcement perspective, I would like to see increasing attention paid to other provisions of the Act … [George Addy, Osler, Hoskin & Harcourt, 59:11:15]

1. **That the Competition Bureau designate conspiracies as one of its highest priorities and that it allocate enforcement resources consistent with this ranking. That the Competition Bureau continue implementing existing enforcement strategies that target domestic and international conspiracies against the public, independently and jointly with competition authorities of other jurisdictions. As a matter of routine, that the Competition Bureau review its tactics of**

[6] However, if the first two complaints are indeed correct, then the third may not be correct.

crime detection with a view to improving its existing record of success.

Framework Legislation and Special Provisions

[A]s has been stated many times, the Competition Act *is a statutory general application. I'm not sure it's still true, with specific provisions now dealing with travel agents and so on, but I think it should be.* [Tim Kennish, Osler, Hoskin & Harcourt, 59:09:55]

The *Competition Act* is framework legislation; it applies to all industries in equal measure (except those monopolies created by the federal or provincial legislations). There are both good economic and legal reasons for this. The economic reasons are the long-standing belief that, by and large, free and open markets provide the best combination of products and services at the best prices to consumers. Except on occasion, when the *Competition Act* or some other (usually industry-specific) statute is needed, the process of competition disciplines suppliers in their decision making and thereby induces them to fulfil the needs of consumers in the most efficient manner. In the cut and thrust of competition, efficient firms survive and prosper, and inefficient firms fail and withdraw. The outcome of this dynamic is that only the interests of consumers and efficient suppliers are protected. The legal reasons are simply that, for constitutional reasons, most industries fall under provincial jurisdiction.

Generally speaking, the *Competition Act* only operates when: (1) the marketplace fails to deliver on the above expectations; and (2) compliance with the Act would produce a better outcome. Such situations arise only occasionally when, owing to technological and/or regulatory barriers, the pre-conditions for healthy competition are not present. In such cases, the Commissioner of Competition does not regulate the outcome, but instead lays the groundwork for a more competitive outcome.

There are industries that warrant special treatment. To the extent that they are regulated, there is a principle of regulated conduct, which is somewhat uncertain in its operation. I think it would be helpful if there were clarification of its operation, but to the extent that an industry is regulated, it is withdrawn from the coverage of the Act. [Tim Kennish, Osler, Hoskin & Harcourt, 59:09:55]

Firms in special industries requiring special dispensation from selected provisions of the Act and/or from competition itself are not ordinarily provided refuge through special rules in the Act. Rather, specific statutes and regulatory regimes, which are usually industry- or firm-specific, are permitted to override the *Competition Act*

This is how the regulated conduct defence was born; although the boundaries of the defence are not clear. More jurisprudence will, perhaps, provide greater clarity in time.

At least this was the case for 111 years of antitrust law in Canada. In 2000, however, the Government of Canada departed from this principle and adopted special provisions that armed the Commissioner with the extraordinary power to issue an interim injunction (section 104.1), or an interim cease and desist order as it is often called, against any air service provider, as defined in the *Canada Transportation Act*, to prevent any anticompetitive behaviour (predatory pricing, paragraph 50(1)(*c*), and abuse of dominant position, section 79). Bill C-23 would extend the duration of this order (beyond a maximum of 80 days if all renewals are put into effect) to allow for good faith, but belated information exchanges between the contesting parties; the bill would also subject an airline company guilty of such offences to an administrative penalty of up to $15 million. The government justifies these measures on the grounds of the current crisis in the competitive structure of the airline industry in Canada.

[T]he government felt that there was a need to add some definition in terms of the airline industries is because of the special characteristic of the airline which is somewhat unique. You've got an industry where you have an overwhelming dominance by a carrier, you've got some restrictions in terms of the amount of foreign ownership that you can have in the industry, you've got assets that can be moved fairly rapidly which could be targeted at new entrance. [André Lafond, Competition Bureau, 64:09:40]

Specialists in competition policy and law are not convinced by the government's arguments. They claim many reasons why special airline provisions are not credible: (1) the crisis is partly of the government's own making, the foreign ownership restrictions prevent competitive entry that would discipline Air Canada's pricing behaviour, moreover, the government also failed to provide the proper institutional framework during the industry's deregulatory transition period; (2) although the cost and pricing structures of airline services are prone to seasonal and other forms of price cutting to equilibrate demand and supply, possibly (but only rarely) leading to predatory price cutting, so are most other transportation services — rail, bus, cruise liners — that are conveniently handled by Canada's transportation regulator, the Canada Transportation Agency; (3) the sheer dominance of Air Canada, with a market share exceeding 80%, is not out of line with that of incumbent local telephone and cable television companies that are currently being deregulated under supervision from the Canadian Radio-television and Telecommunications Commission (CRTC); and (4) the precedent these measures set for other industries seeking

Although every industry … is unique in some way, by and large the kinds of competition problems are fairly generic. You have problems of price fixing and you have problems of abuse of strong market position. You worry about mergers in any kind of industry, so in principle these problems come up or could come up in any industry. [Tom Ross, University of British Columbia, 59:10:15]

special treatment, namely the grocery and newspaper industries, is a slippery slope. These very compelling objections are not exhaustive.

[C]ompetition legislation as it exists in many parts of the world is designed to be a protector of free markets — a referee, so to speak — not a regulator. Regulation is done in industry-specific statutes, and when you mix the two you risk creating not only a hodgepodge but also a series of matrices that may not be effective in accomplishing either generic goal. [Calvin Goldman, Davies, Ward & Beck, 59:10:35]

In its *Interim Report*, the Committee sided against special provisions for the newspaper industry and suggested an alternative approach modelled on the special banking and financial services provider statutes. The Committee also suggested other ways of realizing the government's stated objectives in providing the Commissioner with special interim cease and desist powers with respect to the airline industry — and with respect to all other industries, for that matter — through expanding Competition Tribunal powers under section 100 to cover abuse of dominance and predatory pricing provisions. This option would at least preserve the Act's general application.

I think this is very dangerous … turning this from framework legislation into a regulatory regime put in the hands of somebody who not only doesn't have the resources but who, frankly, is very ill-equipped to deal with it. [Stanley Wong, Davis and Company, 59:11:30]

Although the government has not responded to the Committee's *Interim Report*, its decision not to revoke section 104.1, when Bill C-23 would generalize this power in the hands of the Competition Tribunal, suggests that other policy considerations are at work. For example, although the time required for the Commissioner to seek an interim order from the Tribunal may be quite short, this delay could, in some circumstances, be critical. In any event, the government appears adamant to any return to direct regulation of air services and fares or to unilateral free trade in air carrier services, and is steadfast in its decision to attempt to correct structural problems within the industry through the *Competition Act*.

We have a scenario where we're not quite at the framework model and we're not into regulation, and we're asking the Commissioner, in exercising his powers, to straddle the fence. [George Addy, Osler, Hoskin & Harcourt, 59:12:00]

At this time, the Committee acknowledges that the special provisions related to the airline industry are temporary measures that will be removed when healthy competition is realized within the industry. At the same time, the Committee is deeply concerned that this expectation will be long in coming, as even the United States (with about ten times the population of Canada) appears to be able to sustain only five or six nationally hubbed airline companies. Without the removal of the ownership and cabotage services restrictions, the industry may be destined to dominance by Air Canada for a protracted period. As such, the Committee is apprehensive about the government's move from a law of general application to one that includes special provisions for a specific industry when other equally effective options may be available through forward-looking reform. Moreover,

[Y]ou either have to go in and regulate the business — and if you're going to regulate it, you shouldn't be regulating just Air Canada — or you're going to have to stand back and say "This is a dynamic business … and the chips will fall where they may." Unfortunately, at the moment we're in this really untenable halfway house ... [Lawson Hunter, Stikeman Elliott, 59:10:30]

the government's current policy course is possibly undermining the credibility of Canada's competition regime. Many competition specialists — including international organizations such as the Organisation for Economic Co-operation and Development (OECD) — are beginning to question the Competition Bureau's independence from Parliament and government. The Committee will broach this issue in some detail in the next chapter.

[W]hat I would actually urge the Committee to consider is to look at the airline-specific regulations we have, and look at them for general application. It just happens to be that crisis precipitates change. That's happened before with the Competition Act*, and it's now happening again. But we shouldn't leave it like that. It shouldn't be that Air Canada is bound by special rules, but the Act should be able to deal with any conduct we need to deal with in a partially deregulated industry.* [Robert Russell, Borden, Ladner & Gervais, 59:10:35]

In this report, the Committee will be proposing changes in the abuse of dominant position and predatory pricing provisions (respectively, section 79 and paragraph 50(1)(*c*)) that should satisfy the government, competition lawyers and economists, while providing balanced competition enforcement to the business community and the consuming public. These changes will permit the return of the *Competition Act* to law of general application, with no "special provisions for special industries."

CHAPTER 2: COMPETITION LAW ENFORCEMENT

The State of Competition

At the outset of this report, and in the *Interim Report* as well, the Committee asserted that Canada's economic environment could be characterized as one in which non-compliance with the law is more the exception than the rule. We paid tribute to the *Competition Act*, the Competition Bureau and the Competition Tribunal for this state of affairs. To this list, we could have added the litany of competition lawyers and economists who keep these government institutions abreast of developing trends in the marketplace and the newest analytical techniques used to judge economic behaviour.

I think right now in Canada, when you look at our position … in the world and the economy we're in today, we should be proud of the fact that we have a productive and efficient economy. I think that our Act has served us well in trying to get there. [Robert Russell, Borden, Ladner & Gervais, 65:10:30]

This belief is supported by: the testimony from economists who tell us that, in the main, the *Competition Act* uses modern economic analysis; the Competition Bureau's staff of economists who are well qualified and competent to the task at hand; and the Competition Tribunal's unique expertise in this complicated field. Competition lawyers tell us that, by and large, the *Competition Act*, the Bureau and the Tribunal provide us with as close to an optimal level of due process and economic justice as one could expect. Adding all of these inputs to competition policy and enforcement to the fact that Canada is a relatively open marketplace, we are confident that competition reigns in Canada.

At the same time, the Committee would be remiss in its obligation to the public if it were to conclude that all is well in the competition regime. In fact, the Committee's study of competition policy over the past three years has demonstrated deficiencies and that the regime can be made to work better. But before addressing these systemic issues and making suggestions for improvement, it is worth reviewing the statistical data on enforcement for clues on where our efforts for reform would best be applied.

It may be that in a number of areas we simply don't have that many meritorious cases. [Neil Campbell, McMillan Binch, 59:12:15]

The Enforcement Record

Evaluating the enforcement record of the Competition Bureau requires understanding of both what is being asked of it and, in particular, what market behaviour it can pursue from a practical sense. We are asking the Bureau to pursue all four objectives listed in the purposes section of the *Competition Act*, as well as to uphold the spirit of this Act. Section 1.1 states that the purpose of the *Competition Act* is to maintain and encourage competition in Canada in order to:

- promote the efficiency and adaptability of the Canadian economy;
- expand opportunities for Canadian participation in world markets and recognize the role of foreign competition in Canada;
- ensure that small and medium-sized enterprises have equitable opportunity to participate in the Canadian economy; and
- provide consumers with competitive prices and product choices.

It was my experience that one or two litigated cases by the Bureau, especially if they're large cases, could pretty much wipe out the litigation enforcement budget … This means the Bureau has to be extremely selective in terms of the kind of cases it can actually take on, especially if they're likely to be cases that get complex in a hurry. [Douglas West, University of Alberta, 59:10:10]

These objectives are mostly qualitative in nature and are not amenable to objective measurement; only subjective evaluations are possible. This is why we ask the Commissioner of Competition to report annually on his agency's enforcement and advocacy activities, rather than on his effectiveness in realizing the objectives of the Act. People are then left to form their own opinions on the Bureau's effectiveness in enforcing the Act and realizing its purpose.

In the Committee's view, an evaluation of the Competition Bureau's enforcement record cannot be divorced from the costs of litigation. The Committee was told on several occasions that the Bureau incurs enforcement costs, on average, of approximately $1 million per litigated case.[7] This cost presumably varies according to the type of case, whether a criminal or civilly reviewable practice, a merger or an abuse of dominant position case, an

[7] These comments were confirmed in a recent study commissioned by the Competition Bureau, entitled *Study of the Historical Cost of Proceedings Before The Competition Tribunal (1999),* which involved section 75 and 77 cases.

anticompetitive pricing practice or a conspiracy case, etc. More importantly, however, this large enforcement cost drives a huge wedge between the goal of complete compliance with the law and the economic behaviour we observe in the marketplace; so this cost must, among other factors, figure into the Bureau's enforcement strategy.

I would like to … talk about the generic necessity of ensuring … that the Bureau's resources and institutional framework are indeed as strong as they should be, so the mandate can be carried out in an efficient and effective manner. [Calvin Goldman, Davies, Ward & Beck, 59:09:20]

We must clarify what we are asking of the Bureau. The Committee is not asking the Commissioner and his staff to pursue every case with a positive net economic benefit; nor should the Commissioner strictly engage in profit maximizing law enforcement. Rather, the Commissioner should pursue those meritorious complaints with a substantial economic impact. This will deter egregious anticompetitive behaviour given the resources the government is able to allocate.

There are good reasons to take the last of these three approaches. The first approach would require the Commissioner to pursue all cases that would generate fines in excess of the public enforcement costs. This could require unlimited resources, which taxpayers would be reluctant to pay given the limited benefit each would receive. The second approach, which involves fines reflecting, not their deterrence value, but their profit-making potential, would undermine the public good, which the government and Parliament are entrusted to promote. Canada wants no part in such a litigious society. The Committee is not willing to sacrifice economic justice, nor is it prepared to live with the "chilling effect" on economic activity, which such an unwavering approach implies.

I want to commend the Committee … in setting the scene — the market context within which this market behaviour is being assessed, enforcement decisions are having to be made, and discretion exercised by the Commissioner. [George Addy, Osler, Hoskin & Harcourt, 59:12:55]

In the realm of law and economics, optimizing the benefits of competition requires a balanced enforcement approach, where balance refers to the appropriate measure of pursuit of compliance with the Act. Such an approach recognizes that neither the threat of prosecution nor the education and voluntary compliance measures are by themselves the most effective enforcement strategy. The Committee is convinced that the Competition Bureau is appropriately armed with the array of enforcement instruments needed to ensure compliance with the Act. These instruments range from education through publications, communications and advocacy to voluntary compliance through monitoring, advisory opinions, advance ruling certificates to concerted action through negotiated

settlements, consent orders and prosecution. However, such a balanced approach will be very subjective; outsiders will find it difficult to distinguish good judgment from bad judgment — precisely because the law and economics of market behaviour is not an exact science; and, even if it were, there are numerous other pitfalls in collecting evidence in support of any position on any questionable activity. For all these reasons, the Committee will draw only cautious or the most obvious conclusions from the current enforcement record.

[T]he enforcement of the law would benefit from more resources … Underlying that question is a bigger question — namely, what is the role of the Commissioner, the role people are seeking to have funded? Obviously, there's always the overriding question … that amongst all the other competing public policy priorities, how much do we as Canadians want to invest in the enforcement of competition law? [George Addy, Osler, Hoskin & Harcourt, 59:12:40]

Table 2.1
Competition Bureau Enforcement Record
By Selected Provision in the *Competition Act*

Provision	Complaints	Disposition of Complaints		
		Investigations or Inquiries	Alternative Case Resolution	Formal Enforcement Proceedings
s. 50(1)(*a*)	88	5	4	0
s. 50(1)(*c*)	382	7	9	0
s. 61	461	7	77	3
s. 75	304	27	4	1
s. 77	214	28	7	0
Total	**1,449**	**74**	**101**	**4**

Note: Data on the pricing provisions (paragraphs 50(1)(*a*) and 50(1)(*c*) and section 61) cover the five-year period commencing 1 April 1994 and ending 31 March 1999. Data on refusal to deal (section 75) and tied selling, exclusive dealing and market restriction (section 77) cover the four-year period commencing 1 April 1997 and ending 31 March 2001.

Sources: J. Anthony VanDuzer and Gilles Paquet, *Anticompetitive Pricing Practices and the Competition Act: Theory, Law and Practice*, 1999; Competition Bureau, undated letter to the Committee in response to hearings on Bill C-23.

Table 2.1 provides a partial statement of the Bureau's enforcement record over the past few years by selected provision in the Act. The Committee is aware that many conclusions can be drawn from data, including diametrically opposing conclusions. For example, based on the number of complaints, one might conclude that more vigilant enforcement should be directed against price maintenance violations than any other anticompetitive practice (i.e., refusal to deal, and tied selling, exclusive dealing and market restriction). However, one might just as reasonably conclude that, based on the number of investigations relative to the number of complaints, the Bureau is relatively lax, and possibly too lax, on predatory pricing, refusal to deal, and tied selling, exclusive dealing and market restriction

complaints. Both views are possible given the lack of critical and pertinent facts to each case.

Obviously, the Committee is in no position to quantify the economic fallout of each case. Neither can we assess the relative merits of cases according to the different provisions in the Act; and nor can we gauge the exact legal or economic inadequacies of each provision in the Act. We do understand that different marketing and pricing practices spark different public reactions, and thus lead to different levels of reporting; but there is no way of knowing the exact correlation between the outrage and the number of complaints for a meaningful evaluation. Is the ratio of investigations to complaints with each provision in the law related more to the cost of litigation, merit, economic impact or the clarity of terminology used in the Act?

If we have a lot of behaviour that is offside … it can be reined in by litigated cases or it can be reined in when the Commissioner gets somebody to stop their behaviour because that party knows the alternative is to face litigation. You see the Commissioner settling cases with alternative case resolutions all the time, and that's highly, highly cost-effective for all of us. [Neil Campbell, McMillan Binch, 59:12:15]

The VanDuzer Report broached these very issues in terms of the anticompetitive pricing provisions, and we see no reason to second-guess its main conclusions. The report assessed the Bureau's case selection criteria. There are four, not equally weighted, criteria to which points are assigned to each complaint based on the facts. The criteria are: (1) economic impact; (2) enforcement policy; (3) strength of the case; and (4) management considerations. The Committee highlights the following excerpts from the VanDuzer Report:

> The statistics show that few cases have been pursued to resolution, except through ACR's [alternative case resolution] in price maintenance complaints. The relative absence of formal enforcement proceedings raises several concerns regarding the certainty and, ultimately, the effectiveness of the law. More formal enforcement proceedings would force the courts and the Tribunal to progressively refine the law, making clear its appropriate application as well as signalling the seriousness of the Bureau's intent to enforce it. More cases would also expose the weaknesses in the law which would, in turn, be an important catalyst for law reform. One might hope and expect that increasing certainty brought about by greater formal enforcement activity by the Bureau would encourage greater interest in private actions under

What has obviously happened is that the Bureau has essentially built into its internal case prioritization the principle that cartels are viewed as quite a problem, and price maintenance and price discrimination laws, for example, are viewed as laws that are not economically sound, that are overreaching, and that should not be enforcement priorities. [Neil Campbell, McMillan Binch, 59:11:25]

> section 36. To date the possibility of civil actions alleging violation of the criminal provisions has been little used.[8]

> A disjunction is created between the expectations of people complaining to the Bureau about pricing practices and what the Bureau is prepared to deliver. This is most serious, in relation to price discrimination and predatory pricing, where the complete absence of formal enforcement actions opens the Bureau to the charge that it is choosing not to enforce the Act. This suggests either that the case selection criteria be revised so as to minimize impediments to bringing pricing cases and that the Guidelines be revised to more closely follow the Act or that the provisions be reformed to provide clearer direction for bureau enforcement policy. Either way, the result would be closer coincidence between what the law says and the Bureau's enforcement policy.[9]

I believe they can and do win conspiracy cases in both big and small settings, particularly in the modern environment, with their current immunity program, which allows them to approve the agreements they used to have so much difficulty approving in the 1980s. The pre-1992 statistics really aren't relevant in helping you decide whether you need to do something in that area. [Jack Quinn, Blake, Castles & Graydon, 59:12:40]

More generally, the Committee would like to report that, given the rather steady and holding trend in both the number of all complaints and investigations in the four- and five-year periods considered in Table 2.1, at a time when economic activity was buoyant and growing steadily, the business community has been relatively more compliant with the law. However, we cannot because even the number of complaints is dependent on people's knowledge of what an offence is under the law and their perceptions of the attention the Bureau will give their complaint. Because these important factors are not known nor recorded, we cannot adjust the data accordingly.

In terms of … enforcement issues, there are really three things that can be dealt with … There is this question of funding … There's also the question of alternative enforcement mechanisms like private access … The other area on the agenda … is we need to radically reform the Tribunal process. [Margaret Sanderson, Charles River Associates, 59:11:20]

The record level of fines collected by the federal treasury as a result of the Bureau's recent intensive pursuit of conspiracies could be interpreted as a sign of greater vigilance that will soon pay off in a more robust economic activity based on more efficient firms and the adoption of aggressive, competitive pricing policies. But even here most of these fines can be attributed to convictions made from international conspiracies. The Bureau might be just riding on the coattails of competition authorities of other jurisdictions. Furthermore, guilty pleas in conspiracy cases are just as likely to reflect the high cost of litigation and the potential for private information to be transferred to the public domain in other jurisdictions such as the United States where rivals may seek treble damage awards. These

8 J. Anthony VanDuzer and Gilles Paquet, *Anticompetitive Pricing Practices and the Competition Act*: *Theory, Law and Practice*, p. 70.

9 Ibid., p. 71.

facts suggest guilty pleas are more likely to reflect the cost benefit of going to trial in Canada than actual guilt or the deterrent effectiveness of the law.

It's even more expensive to deal with a criminal proceeding because of the criminal standards. So decriminalization, in some respects, and going to a per se approach should cut the cost down, because overall it's a cost to society. [Robert Russell, Borden, Ladner & Gervais, 59:09:10]

Given the foregoing analysis, the Committee will concentrate its efforts on reforms that will directly lower the cost of enforcement, without unduly compromising legal rights, and thus reduce the wedge between the goal of complete compliance with the law and the economic behaviour we observe in the marketplace. First on everyone's list as a means of reducing enforcement costs is the Tribunal's current processes; these will be discussed in the next chapter. The development of jurisprudence and the Bureau's enforcement guidelines also have a direct bearing on enforcement and litigation costs; their examination will immediately follow this section.

The Committee will also examine indirect impacts on the cost of enforcement. We will review the most contentious provisions of the Act to ensure their legal treatment appropriately reflects their economic motivations and consequences. As such, any shift of important provisions from the criminal to reviewable section of the Act, quite apart from a reduced chilling effect on economic activity such a move might have, may reduce the overall cost of enforcement (see chapters 4 and 5). Furthermore, such changes would undoubtedly shift the burden of enforcement from the Attorney General of Canada to the Commissioner of Competition, and this may, in turn, have consequential budgetary and resource impacts on both these government agencies. In terms of enforcement tactics and formal powers, the Committee will evaluate the merits of a cease and desist order relative to an award of damages and fines as means for deterring anticompetitive conduct, in particular predatory behaviour. Finally, the Committee will examine the impact of granting private rights of action on a limited number of practices covered under the Act's civil section as set out in Bill C-23. The Committee will, at the same time, review the adequacy of resources provided to the Bureau for enforcement of the Act.

Part of the debate … around splitting section 45 into both a per se and a civil offence … [is] … that, it will be more costly for the Commissioner to prosecute a civil offence. Under the criminal model now, responsibility is split between two departments, so there are two budget funds to address the cost of prosecution. The Commissioner's office acts as an investigator, and the Department of Justice acts as the prosecutor. To the extent the role of the Commissioner is revisited, part and parcel of … that should always include the resource implications … to the Bureau. [George Addy, Osler, Hoskin & Harcourt, 59:11:15]

Jurisprudence and Enforcement Guidelines

[T]he way the law evolves is decision after decision … it gets fine-tuned that way. What seems to happen in Canada is a decision that leaves a fair amount of uncertainty, and then nothing happens for eight or ten years. [Donald McFetridge, Carleton University, 59:10:50]

The enforcement of any law, including that of competition, cannot be conducted in a vacuum. Anchors upon which behaviour is assessed are essential; moreover, clear markers distinguishing acceptable from unacceptable market behaviour are required. The economic content of the written law is simply insufficient. Jurisprudence and enforcement guidelines are required to flesh out the sometime abstract economic thinking on which the law is based. Indeed, when jurisprudence and enforcement guidelines properly reflect economic theory, they serve to guide the business sector in voluntarily complying with the law and the Bureau in enforcing it.

I think we need far more testing of the interpretations of the Act made by the Commissioner … not just more powers for the Commissioner. [Stanley Wong, Davis & Company, 59:11:30]

Competition law experts appearing before the Committee reached virtual unanimity on this score. In their opinion, there is simply insufficient jurisprudence to properly guide market participants. Uncertainties in the law and its application abound. Where these competition law experts begin to differ, however, is in terms of the principal cause. Some suggest a weak law is the culprit, while others suggest a risk-averse Competition Bureau is to blame. The rift widens when it comes to the proposed solution of providing greater financial incentives to develop the needed jurisprudence. Some maintain that it would be worthwhile to do so, yet others believe this is an expensive way of realizing greater certainty in the law, preferring instead more clarity in the Bureau's enforcement guidelines. For its part, the Committee will come down the middle on both these issues. We believe that more jurisprudence is needed and this might be partially realized with the implementation of private rights of action, as prescribed in the amended version of Bill C-23. In addition, the Committee recognizes that refinements in the enforcement guidelines are needed.

First, nobody really wants to have to go to court or before the Tribunal for the sheer sake of providing jurisprudence for others. That's kind of a public service that perhaps nobody necessarily wants to provide. [Donald McFetridge, Carleton University, 59:10:50]

The Bureau's enforcement guidelines are meant to fill the cracks in the public's understanding of the law left by insufficient jurisprudence. As the VanDuzer Report, in terms of the anticompetitive pricing provisions, put it:

> Through its Price Discrimination Enforcement Guidelines and Predatory Pricing Enforcement Guidelines the Bureau has attempted to provide, for enforcement purposes, a coherent rationale for enforcing the criminal provisions dealing with price discrimination and predatory pricing. … [F]or the most part, this has been a very effective approach to enforcement. Guidelines are significantly more cost effective than litigation for the purposes of clarifying interpretive uncertainty relating to the provisions of the *Competition Act*. As well, they can deal with issues comprehensively and within an analytical framework, while decisions in individual cases contribute only incrementally to the understanding of the law and the analysis may be tied to the facts of each case. Guidelines increase the likelihood of consistent and accurate decision making by commerce officers who make the difficult assessments of cases at the critical preliminary assessment stage. By disclosing a clear approach to enforcement, guidelines may facilitate ACR's and, more generally, will ease the compliance burden for business.[10]

[I]f there had been more cases, we would not … have so many guidelines. We would not … consider, for example, in section 78, all the illustrative anti-competitive acts or abusive acts that a dominant firm can do. This could have been explored before the Tribunal, and we would see that in the jurisprudence. [Donald McFetridge, Carleton University, 59:10:50]

From the business community's perspective, the guidelines are not reassuring. The guidelines have never been binding on courts, the Competition Tribunal or the Bureau. It was reported to the Committee that the Tribunal routinely ignores the guidelines; recently, the Competition Bureau abandoned its own merger enforcement guidelines in the *Superior Propane* case. The Committee finds this disconcerting; we can only conclude that the enforcement guidelines need to be revised. The VanDuzer Report made a number of specific recommendations on the Bureau's enforcement guidelines, which, in general, we support; however, the Committee will sort out each in later chapters. The Committee also agrees with the VanDuzer Report's recommendation 16 that deals with the enforcement guidelines in a general sense. This recommendation follows from the recognition of a general shift from an industrial economy to a knowledge-based economy characterized by innovation and industrial structures in which market dominance, when it occurs, is likely to be relatively short-lived. The Committee, therefore, recommends:

I think the elements are in the Act. I think the interpretations are very poor. I don't think you need separate rules for separate industries. But I do think you need clear and consistent application of clear guidelines. [John Scott, Canadian Federation of Independent Grocers, 59:09:45]

[10] J. Anthony VanDuzer and Gilles Paquet, op.cit., p. 86.

2. **That the Competition Bureau review its enforcement guidelines, policies and practices to ensure appropriate emphasis is placed on dynamic efficiency considerations in light of new challenges posed by the knowledge-based economy, including factors such as: (1) high rates of innovation; (2) declining or zero marginal costs on additional units of output; (3) the possible desirability of market dominance by a firm where it sets a new industry standard; and (4) the increasing fragility of dominance.**

Our experience is that the guidelines are … ignored when it comes to a specific case. We have the example recently of the Competition Bureau abandoning its merger enforcement guidelines when it came to arguing the Superior Propane case. We have other cases in which the Tribunal has taken no notice of guidelines. … But to think that guidelines … will necessarily result in less uncertainty … I think only jurisprudence can do that, and we don't have a heck of a lot of it. [Donald McFetridge, Carleton University, 59:10:05]

Once these revisions are completed, we expect the Commissioner of Competition to keep to the enforcement guidelines. Major deviations from them are not acceptable. If further changes are required, the enforcement guidelines should first be amended then enforced, not the other way around.

"Time is of the Essence" Enforcement Tools

If you were on the inside and if you saw the difficulty and extent to which they have tried to comply with this law, I think you would come to the conclusion that the answer is, yes, it is effective, the Commissioner is very vigilant, and Air Canada has struggled daily with trying to understand what they can and can't do under the current regime. [Lawson Hunter, Stikeman Elliott, 59:09:45]

On a number of occasions before the Committee, the Commissioner of Competition has argued for amendments to the law granting him new powers to issue cease and desist orders of his own right, without allowing the affected party a right to be heard prior to the making of the order, and without any authorization from the Competition Tribunal. Such a power was granted under section 104.1 of the *Competition Act* in respect of any domestic air service, as defined in the *Canada Transportation Act*, in terms of any anticompetitive behaviour (predatory pricing, paragraph 50(1)(*c*), and abuse of dominant position, section 79). Bill C-23 would extend the duration of this order (beyond a maximum of 80 days if all renewals are put into effect) to allow for good faith, but belated information exchanges between the contesting parties. Bill C-23 would provide this same power (adding a new provision, subsection 103.3(2)) to the Competition Tribunal in respect to all industries and all civilly reviewable conduct in the Act.

A new subsection 103.3(2) in the Act specifies the circumstance in which the Tribunal may make an interim order. The order may issue if:

- An injury to competition will occur that cannot be adequately protected by the Tribunal.
- A person is likely to be eliminated as a competitor.
- A person is likely to suffer: a significant loss of market share; a significant loss of revenue; or other harm that cannot be adequately remedied by the Tribunal.

Critics mention that the *ex parte* procedure — without notice to any other party — presents, as a *fait accompli*, an order that has the same force as a court order and a breach of which is punishable by fine or imprisonment. Once the order is made, the party may bring an application to set the order aside. In normal litigation practice, motions and applications made *ex parte* are the exception rather than the rule. Moreover, the test that is asked of the Tribunal in granting the order, particularly that of a significant loss of market share or a significant loss of revenue, is so low a hurdle that it treads on having the Commissioner cross over the boundary of protecting the process of competition to protecting individual competitors. This concern is supported widely across the economics field because of the strongly held belief that competition by its very nature means that there will be winners and losers in terms of revenues and market share. Thus, the *Competition Act* now risks interfering with the competitive process. As an alternative, these critics argue in favour of an award of damages and possibly fines as the appropriate method of deterring anticompetitive behaviour.

For his part, the Commissioner believes that these extraordinary powers are necessary owing to the inadequacy of the procedures and/or the remedies currently available to the Bureau to use against the threat of price predation and other anticompetitive conduct in a timely fashion. The *ex parte* procedure is adopted because the alternative of providing notice of the proceedings would impose a process that would involve the Commissioner in time-consuming litigation before the Tribunal in support of the interim order, which would significantly reduce the "time

I just want to distinguish between two ways of dealing with predatory pricing. One is the cease-and-desist type of power the Commissioner has and is maybe trying to have enhanced … to a "Don't even think about it" power, which would be issuing orders in advance of the incumbent firm even doing anything. That's one way to go, and it can have the virtue of appearing to protect a specific competitor and make sure they don't get hurt in the short run. I think it's definitely the wrong way to go, whether it's airlines or any other industry. [Donald McFetridge, Carleton University, 59:10:40]

I think the way to deal with predatory pricing is to wait and look at the offence. I think where we have a problem in this country is that it doesn't do much good after finding that an offence has been committed if we take the civil branch and abuse of dominance and say, "Well, don't do it again", and then issue an injunction. That type of remedy is simply insufficient. I think what we really want … is to use the civil branch and use fines. And ultimately, perhaps … damage awards. [Donald McFetridge, Carleton University, 59:10:40]

is of the essence" aspect for which the power is being sought.

There's the predatory pricing. Clearly, you need a remedy besides cease and desist. A remedy based on damages and fines seems to be a sensible deterrent. [Jeffrey Church, University of Calgary, 59:10:55]

In wrestling with these arguments, the Committee recognizes that, in a perfect world where all predatory and other anticompetitive behaviour could be easily detected and there would be no uncertainty in the application of the law, there could not be any predation or anticompetitive behaviour. The cease and desist order would stop this anticompetitive behaviour the minute it started and an award of damages and fines from the Tribunal would remove any incentive to engage in such anticompetitive conduct in the first place. Both enforcement methods — an interim cease and desist order and an award of damages and fines — have a similar impact in such an environment. However, in our imperfect world, enforcement methods are not equivalent; each has a different impact. In a world where "Type 2 errors" are possible (where an enforcement action is taken but should not have been), the interim cease and desist order will impair the process of competition and impose losses on consumers by forcing them to pay higher prices for the period of the order. On the other hand, in a world of uncertain application of the law or a flaw in the design of the law, damage awards and fines may chill rivals from engaging in aggressive but pro-competitive pricing strategies. Clearly, these impacts are not the same.

[T]here's a fallacy in … saying … that the cease-and-desist powers … because they act very quickly, are necessarily desirable. … It is perfectly possible to have an enforcement provision against predatory pricing through the Act, working through the normal process with the Tribunal, not using any injunctive relief. Provided one introduces fines and makes the disincentives for a conviction high enough … [Roger Ware, Queen's University, 59:12:15]

In assessing the pros and cons of these "time is of the essence" enforcement tools, the Committee looks to the data, which clearly show that predation is often alleged but seldom occurs. Between 1994 and 1999, there were 382 cases of alleged predatory behaviour, but the Bureau found only 7 deserved investigation. Nine were solved by alternative case resolution (ACR) and none justified prosecution. Although the high incidence of allegation would favour the damages award and fines enforcement method, the Bureau's decision to investigate only seven cases brings somewhat back into balance the choice of either method (assuming that we are willing to live with prosecutorial discretion to achieve this balance, rather than a systemic basis for balance). At the same time, the Committee is unaware of any incidences of the "chilling" pro-competitive behaviour that the current competition regime has had on the business sector, let alone what incidences of chilling

might arise from a deterrence system based on an award of damages and fines.

Although lack of information does not permit the Committee to judge which of the two enforcement tools would be better, other considerations suggest that this debate need not be framed in an either-or context. Adopting both enforcement methods has a number of advantages: (1) a cease and desist order would help mitigate damages in egregious predatory cases; (2) an award of damages and fines would rebalance the incentive structure to better deter such behaviour when anticompetitive opportunities present themselves (in turn reducing the opportunities for the exercise of prosecutorial discretion); and (3) the special airline industry provisions would become redundant and thus could be repealed. This third advantage is particularly appealing to the Committee, as it would hasten the return of the *Competition Act* to a law of general application. With the adoption of other reforms, as laid out in this report, the Committee is convinced that more jurisprudence would reduce both any uncertainty in the law and its chilling effect on aggressive but pro-competitive pricing practices. For all these reasons, the Committee recommends:

You need to create that type of penalty in the abuse-of-dominance provisions of the Act to retain the deterrence effect of the law. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:12:20]

3. That the Government of Canada empower the Competition Tribunal with the right to impose administrative penalties on anyone found in breach of sections 75, 76, 77, 79 and 81 of the *Competition Act*. Such a penalty would be set at the discretion of the Competition Tribunal.

These changes will permit the return of the *Competition Act* to law of general application, with no "special provisions for special industries." For this reason, the Committee recommends:

What we have right now is a Commissioner of Competition who by statute is independent and reports to the Minister of Industry but who takes no direction from the Minister of Industry other than for the purposes of starting an inquiry. [Stanley Wong, Davis & Company, 59:11:30]

4. That the Government of Canada repeal all provisions in the *Competition Act* that deal specifically with the airline industry (subsections 79(3.1) through 79(3.3) and sections 79.1 and 104.1).

Commissioner Independence and Accountability

A particularly surprising (and disturbing) issue — that of the Commissioner's independence from government — surfaced around the time of the Committee's first set of hearings in 2000. This issue continued to percolate and has since boiled over to include questions of accountability. Doubts on the Commissioner's independence first arose when the Commissioner conducted a review of his own merger enforcement guidelines, as they would apply to the banking sector at the request of the Minister of Finance, suggesting that he too had reservations on their general application. The questions began to multiply as the Commissioner acquiesced to the government a second time when he sought extraordinary cease and desist powers to deal with potential predatory behaviour on the part of Air Canada — once again putting into doubt the Act's general application. More recently, in the *Superior Propane* case the Commissioner abandoned the very merger enforcement guidelines that he confirmed as fit to the Minister of Finance.

What we have now is really decision-making in the hands of a single individual who is really unaccountable. Every time we see an unsuccessful case, there is immediate pressure to amend the Act. [Stanley Wong, Davis & Company, 59:11:30]

However, the Committee does not share all these views and believes that it is important to distinguish perception from reality. In terms of independence, a consensus within the competition law community appears to have formed on the belief that the Commissioner is indeed independent from government in terms of case selection, administration and disposition. The Commissioner is not independent from government in terms of his budget and reporting obligations.

Essentially what's happened in … cases, where speed is of the essence, such as predatory pricing … the Commissioner has been concerned that the process doesn't work expeditiously enough; therefore he's sought additional powers, turning his own office into an investigator and an adjudicator. As soon as a single body is performing both of those functions, concerns are going to be raised about independence. So if we can solve the adjudication model, if we can have the Tribunal play a more active, effective role as an independent check, and procedurally allow it to balance these concerns … its very important that there be … an expeditious process and … a full due process for the various parties. [Margaret Sanderson, Charles River Associates, 59:11:55]

On the matter of enforcement direction, no one could point to any case where the government intervened in the Commissioner's enforcement decision making. On the matter of the Competition Bureau's organization within government, the Committee understands that the Commissioner is subordinate to the Minister of Industry and Cabinet so that, at the end of the day, the government can be held to account to the people for the actions of the Commissioner, one of the most influential public servants in Canada. For example, from time to time, competition experts have judged the Commissioner's enforcement record based on what they call Type 1 and Type 2 errors. A Type 1 error is defined as not taking an enforcement action when there should have been (the market behaviour in question was

anticompetitive). A Type 2 error, on the other hand, is defined as taking an enforcement action when one should not have occurred (the market behaviour was benign from a competition perspective). However, there is also a Type 3 error. The Committee will define this error as wasting the taxpayer's money through inefficient enforcement action. After accounting for deficiencies in the law, at the Competition Tribunal and in his budget, for which the government may be held accountable, any remaining deficiencies in enforcement may be attributable to the Commissioner and his administration of the Competition Bureau. This error can only be corrected by executive decisions and thus institutional independence from government is not advised.

There are really two important things about enforcement policy … One is independence and the other is accountability. The Commissioner needs to be independent, needs to have the resources required to do the job, but needs to be accountable, too. That means we have to be able to go to Tribunal and test the Commissioner's decision. That's one way of keeping him accountable. [Jack Quinn, Blake, Castles & Graydon, 59:11:45]

On the matter of accountability, competition law experts identified a number of ways the Commissioner might be held to account for his enforcement actions. We have already mentioned his accountability to the people through the government of the day. He is also accountable to the people through Parliament — and specifically by way of appearance before this Committee. Beyond bureaucratic means, the Commissioner is accountable for his enforcement decisions to the Competition Tribunal, which can rescind or vary all civilly reviewable decisions he makes, as well as judge his request for a cease and desist remedy.

The Commissioner is independent today in exercising enforcement direction. He is not independent from an institutional perspective. The deputy minister owns his people, so the staff and organization budgeting is all subject to the Department of Industry's priorities. … [W]e should ensure he has both institutional and enforcement independence. [George Addy, Osler, Hoskin & Harcourt, 59:12:00]

If there is weakness in the accountability regime, it has been in decisions not to take an enforcement action with respect to civilly reviewable matters. However, the Committee is confident that forthcoming private rights of action — with the adoption of Bill C-23 — will partially address accountability with respect to sections 75 and 77. In terms of mergers — that is, on the release of private information relating to a merger proposal where no enforcement action is taken — the Commissioner must perform a careful balancing act. He must weigh the merger participants' privacy rights with that of the public's right to know. According to the competition law experts appearing before this Committee, there is little issue here, but they do note that both U.S. and European competition authorities are more forthcoming in providing information than Canada's Competition Bureau. However, the Committee must reiterate the point that Canada, as a small market, is and should be more lenient on mergers relative to larger

The Commissioner … is one of the most highly accountable officials in the Government of Canada, and that comes in part from his oath under the Act and it comes in part from … your ability to take him to court on a judicial review. It comes in addition from the fact that any six residents can force him to conduct an inquiry and can go to the Minister of Industry and ask … to reopen an inquiry that's been discontinued. [Neil Campbell, McMillan Binch, 59:11:55]

Another very important part of his accountability comes from this committee, which has put the Commissioner under a spotlight for the last three years. We've had numerous studies and we have the Commissioner appearing and taking questions and justifying what he does and does not do on a literally monthly basis … You play a very significant role, and you should be continuing to ask him how he's performing with respect to policy and the general administration of the Act. [Neil Campbell, McMillan Binch, 59:11:55]

jurisdictions, including on issues of information disclosure. At the margin, strategic market information released to the public is of less value in larger and less concentrated markets. Finally, this leaves only section 79, the abuse of dominant position provision; here, the public itself has been most vocal, and parliamentarians have heard them loud and clear and this has spurred many amendments for reform.

Private Rights of Action

A limited private right of action currently exists in respect of criminal matters, but such action has been rarely initiated. Under section 36 of the *Competition Act*, a person may bring an action for damages (and costs) if the person has suffered loss or damage as a result of either: (1) conduct contrary to Part VI ("Offences in Relation to Competition"); or (2) the failure of a person to comply with an order of the Competition Tribunal or of another court under the Act. Accordingly, a right of private action for damages may arise in three circumstances:

[W]e do have a leverage problem in the context of a merger or in the context of an abuse-of-dominance inquiry, where the Commissioner's say-so often governs, particularly for parties who are in a small market and have difficulty looking at the current costs and time of a Tribunal proceeding. That is why it's important to streamline the Tribunal process. [Neil Campbell, McMillan Binch, 59:11:55]

1. The Department of Justice successfully prosecutes a violation of a criminal provision under Part VI (conspiracy, bid rigging, price discrimination, price predation, false advertising, deceptive telemarketing, double ticketing, pyramid selling, or price maintenance).
2. After the Commissioner and a party have entered into a consent order, a court has issued the order, and the party fails to comply with it.
3. If an aggrieved party succeeds in a private prosecution.

Under current law, the Commissioner of Competition is the only party with standing to make an application for civil review before the Competition Tribunal. But this is about to change. After considerable study, the Committee amended Bill C-23 to allow private parties to have access to the Tribunal for resolving disputes on a limited number of civilly reviewable business practices: refusal to deal (section 75); and tied selling, exclusive dealing and market restriction (section 77).

One other way to bring more resources into enforcement and to get more jurisprudence is the issue of private actions and allowing standing for private actions before the Tribunal. [Donald McFetridge, Carleton University, 59:10:55]

Witnesses appearing before the Committee on Bill C-23 were generally supportive of amendments leading in this direction. The main argument against private access

was the potential for abuse in the form of "strategic litigation" that is, legal action commenced not for the purpose of seeking a remedy to anticompetitive behaviour, but rather to gain an advantage over a competitor. The Committee, however, is satisfied that the safeguards included in Bill C-23 adequately address these concerns.

Throughout the Committee's hearings on the *Competition Act* there was broad agreement on the principle of granting private access to the Tribunal; there was less consensus on the relief that should be available. Many witnesses did support a right to claim for damages, yet others did not. The Committee therefore ran with the consensus it did obtain, proposing to limit the plaintiff to injunctive relief. As previously stated, the primary reason for denying claims for damages would be to discourage strategic litigation. In the longer term, however, we believe damages and maybe even fines will be necessary to realize effective enforcement.

I'd just point out that the costs for a plaintiff to bring a case to a conclusion are very substantial, and that is all the more an issue for small and medium-sized enterprises. So they most definitely will need to continue to use the Commissioner as the point of first contact on competition cases. I don't think private actions will be a solution to the resource issue, or indeed really to the accountability issue. [Neil Campbell, McMillan Binch, 59:11:55]

The expected benefits of private enforcement differ slightly based on whom you believe. Some argue it will bring a litany of cases which the Bureau does not have the mandate or resources to pursue. Private enforcement will complement public enforcement and, perhaps, generate savings that will stretch the Bureau's current enforcement budget. Yet others believe it will bring only a very limited number of cases; however, these will be pivotal cases that will enrich our body of jurisprudence; bring more certainty into the law; and discourage anticompetitive behaviour that might otherwise slip between the cracks of law and practice.

The Committee believes that, with only injunctive relief as the carrot, private parties in most cases may only be exchanging the costs associated with the alleged anticompetitive conduct for litigation costs (hopefully less than $1 million per case on average with reforms in Tribunal processes). Indeed, if this scenario does in fact unfold over the next few years, it will very quickly become common knowledge across the business sector and Canada will be no further ahead. Rights with no value attached to them are but window dressing — something that, as many observers have described, has adorned Canada's antitrust Acts for too long.

Competition Bureau Resources

A number of witnesses suggested that the enforcement problems in competition policy being encountered by Canada are not solely the result of inadequate legislation, but also stem from a lack of sufficient enforcement resources allocated to the Bureau. Moreover, some witnesses claimed that the Bureau has staff retention problems due principally to low salaries compared to what some of its veteran staff could earn in the private sector doing similar work, or following other pursuits. In fact, these commentators identified a number of reorganization models to get around this recruitment and retention problem, but they failed to provide an assessment on any weaknesses from which these models are likely to suffer. The VanDuzer Report further pinpointed a shortage of, and consequently the need to acquire and develop, industry-specific expertise to complement enforcement officers and ensure that they can make accurate assessments in a timely manner. In these witnesses' opinion, learning on the job is not always efficient.

[W]hen the mandate itself was unfolding — and the mandate was not as broad as it is todal — I can assure you the challenges that face one individual at the top of the Competition Bureau are such that … they warrant consideration of a three-person body. [Calvin Goldman, Davies, Ward & Beck, 59:09:15]

However, the Committee is also aware that part of the enforcement problem over the past decade was the result of uncontrollable factors such as the deregulation and liberalization of transportation, telecommunications and energy sectors. Increased funding in this period did not match the increased responsibility that these developments imposed on the Bureau. A second uncontrollable factor was the unforeseeable merger wave, which, as a number of witnesses remarked, seems to be abating and is mostly behind us now. The Committee believes the Competition Bureau does need additional enforcement resources to fulfill its mandate in an effective manner and, therefore, recommends:

I would suggest that the Bureau cannot be effective … without adequate resources in trying to administer a law of general application in an environment that is increasingly deregulated. They need the resources to act in a properly informed manner. That doesn't necessarily mean bringing many more cases. [Calvin Goldman, Davies, Ward & Beck, 59:10:50]

5. That the Government of Canada provide the Competition Bureau with the resources necessary to ensure the effective enforcement of the *Competition Act*.

Deterrence: Crimes, Fines and Jail

Probably the single most important enforcement instrument in Canada's competition policy toolbox is the

court fine. Unlike cease and desist orders that prohibit future use of a practice, fines levied by the Court have the dual purpose of punishing the assailant and deterring others considering the same anticompetitive activity. Jail time — which is also an important deterrence weapon — has played a relatively minor role. Together these enforcement instruments are used only in the most egregious criminal cases.

When we've had $150 million worth of fines under this section in the last few years, you need to be careful about saying that the law doesn't have sufficient strength. [Lawson Hunter, Stikeman Elliott, 59:09:20]

In Canada, corporations or individuals found in contravention of the general conspiracy provision (section 45) may receive fines of up to $10 million per offence, and individuals can face up to a five-year jail term. These fines are among the most severe found in the world. Fines for bid rigging (section 47) are set at the discretion of the Court, which is not constrained by a maximum monetary penalty. On the other hand, an historical examination of actual fines assessed by the Court shows that they had not even come close to the maximum permitted; however, the most recent past is marked by a sharp increase.

In 1990, the Manitoba Court of Appeal held that the earnings of the accused are relevant in assessing a fine and promptly raised the initial fine from $100,000 to $200,000 in a case involving price maintenance (paragraph 61(*a*)) and gasoline distribution. In terms of bid rigging, eight flour milling companies were assessed fines totalling $3.4 million in 1990. Furthermore, the largest conspiracy case in Canadian history — an international cartel to fix prices of bulk vitamins — netted the government $91.5 million in 1999-2000. Finally, the aggregate data indicate that, since 1980, convictions in 32 cases under the conspiracy provision (section 45) yielded fines totalling $158 million; $14 million in penalties was levied under the foreign directives provision (section 46); and a further $8.8 million was levied under bid rigging (section 47). More than 80% of these fines were collected in the past two years alone as a result of guilty pleas by large multinational corporations engaged in global conspiracies.

When you think about the biggest multinational companies in the world coming and paying attention very closely, after the United States, to Canada, paying huge fines and having individuals pleading guilty to crimes in Canada, that is fairly remarkable. I think the Bureau is a very credible enforcer on the world stage on cartels. It has also done perfectly well on local cartel activity in Canada. It has sent people to jail. It has obtained convictions. [Neil Campbell, McMillan Binch, 59:12:55]

The Committee is pleased with Canada's recent enforcement record. Although we remain concerned that some conspiracies could possibly earn more than the $10 million maximum fine they would be subject to pay if

caught, the Bureau contends that the business community does not take these fines as a “licence fee” or as simply another cost of doing business.

CHAPTER 3: COMPETITION TRIBUNAL

Tribunal Organization and Composition

The Competition Tribunal was created in 1986 as part of the major reform of Canada's competition law that saw the *Combines Investigation Act* replaced with the *Competition Act*. The Tribunal is a specialized court combining expertise in economics and law that hears and decides all applications made under Parts VII.1 and VIII of the *Competition Act* (including merger review, abuse of dominance and other reviewable trade practices). It is an adjudicative body, operating independently of any government department, and is composed of not more than four judicial members and not more than eight lay members. Judicial members are appointed from among the judges of the Federal Court, Trial Division, while lay members are appointed by the Governor in Council on the recommendation of the Minister of Industry.

You should look going forward at opening up the system to allow participants more access to the Tribunal. I find it hugely ironic that in an act devoted to competition the Commissioner has a monopoly or near monopoly on access [John Rook, Osler, Hoskin & Harcourt, 65:10:45]

The Tribunal deliberates on complex questions of economics and law, and makes decisions affecting not only the rights and economic well-being of the parties, but having implications for businesses and consumers in Canada and abroad. In order to be able to adjudicate on these matters, the Tribunal is given the same powers found in a superior court of record, including the power to hear evidence, summon witnesses, order production and inspection of documents, enforce orders, and generally to do whatever is necessary to exercise its jurisdiction. Ultimately, these procedures serve one aim: to ensure that the Tribunal is able to gather the evidence it needs to make a just and correct decision on the facts of the dispute. The Tribunal does not gather evidence or facts; rather, it relies on the parties themselves (or more commonly, their lawyers) to collect and present the evidence it needs to make a decision. Parties adduce their evidence, each trying to prove their case. Parties are also given the opportunity to "test" their opponent's evidence in cross-examination. This system — known as the "adversarial" model — is used commonly by Canadian courts as well as by other adjudicative bodies.

By and large, most and virtually all of the experience of the Tribunal is on the part VIII side, in particular mergers. Remember, in the 1986 amendments mergers were decriminalized, put into the non-criminal section, and given into the exclusive jurisdiction of the Competition Tribunal. [Stanley Wong, Davis & Company, 65:09:10]

[T]he Tribunal doesn't have a lot of experience. This body was created in 1986 and really started operating in 1987. The first contested case of mergers went in 1990. Now, we've not had that many cases. If you look at the experience of the United States or even the European Union, we don't have a lot of cases, so the significance of every case is magnified. [Stanley Wong, Davis & Company, 65:09:10]

In the "adversarial" tribunal system, the Commissioner of Competition is one of the parties, initiating cases by making an application to the Tribunal. Therefore, the Tribunal and Bureau operate in a manner wholly independent and separate from each other. There is no sharing of resources or consultation on proceedings outside of the formal dispute resolution process. Indeed, this strict separation of functions is considered essential to preserve the integrity of the decision-making process. The Committee is aware that other jurisdictions (notably the European Union) employ a different model, one that fuses the role of investigator and adjudicator. The Committee is of the view that our current model is correct and appropriate, having regard both to the operational dynamics of our system of law, and to the requirements of the Canadian Charter of Rights and Freedoms. Moreover, the separation of functions in the adversarial system produces consistently good and just results. However, the system can be quite slow and procedurally intense. The proceedings are also frequently made more complex by the presence of multiple parties and interveners, as well as the need to consider interlocutory motions on issues of procedure. Contested proceedings often involve very complex issues of economics, i.e., determining market definition, market power, barriers to entry, etc. Parties will frequently retain many experts to address every facet of the economic debate. These experts may produce reports and may give evidence before the Tribunal that will be subject to cross-examination. At least in some measure, the high cost of proceedings before the Tribunal is attributable to what appears to be an increasing trend towards hiring more and more experts. Some witnesses, however, remarked on an increasing tendency of expert witnesses to advocate on behalf of their client, i.e., asserting conclusions of law, rather than limiting themselves to their proper role of assisting the Tribunal in arriving at correct findings of fact.

[W]hen we talk about truncating the procedures or having special procedures for the Tribunal, we should not forget that what we're dealing with is commercial litigation within a certain sphere. We have a lot of history in our courts, if not in our Tribunal, on how to manage those things, and we have various models, not only in Canada, but in other jurisdictions like the U.S., where they have started to manage commercial litigation more effectively and more efficiently. [Robert Russell, Borden, Ladner & Gervais, 59:09:10]

In a lot of the thinking about what sort of process we want to have in the Tribunal, there is typically an attempt to impose a full-blown traditional trial model. That kind of enforcement activity is not appropriate in a public law enforcement context. [Jack Quinn, Blake, Castles & Graydon, 59:12:30]

The Committee is particularly aware that the high cost of Tribunal proceedings may discourage small and medium-sized enterprises from bringing meritorious cases to the Tribunal. The Committee heard little evidence on costs awards, but the Tribunal appears to have broad discretion in this regard; in fact, the Tribunal need not award any costs in

a proceeding. Perhaps, the public would benefit from an expressed policy on costs awards. Accordingly, the Committee recommends:

6. **That the Competition Tribunal develop and articulate a policy to allocate costs in a fair and equitable manner having regard to the resources available to the parties to the proceeding. That such a policy consider the merits of exempting small businesses from liability for costs in Tribunal proceedings.**

I have perhaps been a lone voice in suggesting that this is a tribunal where judges have not played a helpful role in the sense that they have formalized and judicialized it. I would prefer to see a tribunal that really is administrative and that could make decisions more quickly on an expert basis. [Neil Campbell, McMillan Binch, 59:11:25]

Many of the witnesses appearing before the Committee, both in the context of the study in June 2000 leading to the *Interim Report* and during our most recent roundtable meetings, expressed a measure of dissatisfaction with the Tribunal adjudicative process. At the same time, however, witnesses were quick to point out that the system is, on balance, a very good one, and not in need of major reform. The timeliness of interim relief as well as the time required to reach decisions were two problems identified. Furthermore, the costs of bringing a case to the Tribunal appear to many to be excessive, owing in some part, it seems, both to an overly procedural discovery process, as well as to the lengthy lists of expert witnesses the parties are permitted to call to give evidence.

Timeliness

With respect to the criticism that the Tribunal fails to provide interim relief in a timely way, the Committee anticipates that this problem will be addressed in great measure by the new powers conferred on the Tribunal in section 103.3 of the Act by Bill C-23. The new powers will permit the Tribunal to make an interim order to prevent certain anticompetitive practices. The legal test for the granting of the order is quite low — the Commissioner is not required to show that competition will be irremediably harmed, but merely that a person is likely to be eliminated as a competitor, or that a person is likely to suffer a significant loss of market share, revenue or other irremediable harm.

[O]ur ability to get good enforcement in the sense of formal proceedings does depend in part on streamlining and improving the Competition Tribunal proceedings without undermining the ability of people to make a defence for the particular activity they have. … [A]n administrative tribunal, an expert tribunal, would be a much more useful structure. [Neil Campbell, McMillan Binch, 59:11:25]

The Committee believes that granting any manner of relief — interim or final — merely on the grounds that a

[T]he Tribunal decisions have taken far too long. … The most recent consent case, which was done with agreed statements of facts and a high degree of collegiality among counsel on both sides, took something like 18 months on a consent basis. It took 18 to 20 months on a merger. [Stanley Wong, Davis & Company, 59:11:30]

competitor is losing revenue (something which happens all the time, and which is not, in itself, evidence of any anticompetitive activity) represents a serious departure from the well-established and important principle that competition law aims at protecting competition, not competitors. However, the relief contemplated here is *temporary* and is meant to allow the Commissioner to prevent a competitor from suffering immediate and irreparable harm, i.e., being forced out of the market. So, although the interim order may, on occasion, result in inefficiency by protecting an uncompetitive competitor, this impact will, in any case, be temporary. The Commissioner or applicant will still be required ultimately to prove the substantive elements of the relevant section in order to get an order in the final result.

The Tribunal process needs to be streamlined and improved quite dramatically. … There have been four contested mergers before the Competition Tribunal. The average time the Bureau has dealt with those transactions has been about eight and a half months … [and] the average was 19 months from the start until the remedy. [Margaret Sanderson, Charles River Associates, 59:11:20]

Still, the Committee is concerned that setting the bar for interim relief so low may prompt the Commissioner to seek interim relief in cases of questionable merit, with perverse results on competition. In a normal civil proceeding, this would be less likely to occur because the party who applies for the injunction does so subject to an undertaking that, if he loses the case in the final result, he will have to pay the damages accruing to the other person as a result of the injunction. This rule is designed to prompt the party seeking the injunction to take a hard look at the merits of the application. However, this important disincentive does not appear to exist in the *Competition Act*. Moreover, even if such a rule were implemented, it would not necessarily have the desired effect, since the damages payable by the Commissioner to the injured party would be payable out of government revenues, not out of the Commissioner's own pocket (as would be the case with a private litigant in normal civil proceedings). As such, the Commissioner has very little "downside" to seeking an interim order and there is little to make the Commissioner accountable for his decision to seek interim relief.

By having a rules committee, you don't have to have a wholesale set of rules drafted, which may take five years to do, because this is a complex area. You have an incremental process to move the rules along with the change in the law, with the change in procedures, with the change in technology that allows us to adapt to that. [Robert Russell, Borden, Ladner & Gervais, 59:09:35]

In addition to the issue of the timeliness of *interim* relief, there is also the issue of the timeliness of *final* relief, the Tribunal's final order. In the case currently before the Tribunal involving the Commissioner's allegation of abuse of dominance by Air Canada, we see that interim relief was swift. The final resolution of the matter, however, appears to be a long way off. The Commissioner issued a section 104.1 order on 12 October 2000 and extended it for a further 30 days on 31 October 2000. The Tribunal

subsequently extended the order to 31 December 2000. The Committee is disturbed to learn that the hearing is not scheduled to commence until fall 2002. Justice delayed is justice denied. We believe that the resolution of this matter is important for all Canadians.

What has fuelled a lot of the acrimony in litigation before the Tribunal is the sense that there is an imbalance of information and power between the Commissioner … and respondents … This concern is very pointed at the moment, or will become so by virtue of the amendments to Bill C-23, because Parliament has seen fit to give the Commissioner the power to seek an interim order on very limited grounds, ex parte ... [John Rook, Osler, Hoskin & Harcourt, 65:09:45]

Procedural Fairness

Owing to its "high stakes" proceedings, the Tribunal aims to ensure that the procedures it implements are sufficient so that litigants receive the appropriate degree of procedural fairness. "Procedural fairness" refers to the rights and obligations that flow from a party's right to have "due process" (as it is called in the United States) in an quasi-judicial adjudicative setting. Procedural fairness, at a minimum, usually involves the right of a party to tell his story to an impartial (i.e., unbiased) decision-maker; and the right to expect that the decision-maker will act in accordance with applicable laws. If the decision-maker does not act according to his legal authority, then the party would have a right to apply to a court for judicial review (reconsideration of the issue by a court).

The lawyers always argue for more protections, more safeguards, more hearings, and more redeterminations. [Jack Quinn, Blake, Castles & Graydon, 59:12:30]

The essential question of procedural fairness is: how far does it go? Does it permit the rule maker (in this case, the Tribunal) to make rules limiting the scope of examination for discovery, or the time to complete it? What about time limits on presenting one's case? Or limits on the number of expert witnesses one can call to give evidence? Indeed, can "corners be cut" at all without prejudice to the rights of parties?

By providing the appropriate degree of procedural fairness, the Tribunal aims to ensure that parties appearing before it are able to present their case adequately. Traditionally, each party has the right to determine how best to present its case; courts are generally reluctant to intervene unless it is absolutely necessary.

Whichever side of a case we're on, we can be unhappy. We always do that in the courts, but nobody has ever suggested we abolish the courts or limit the powers of the courts in their area of jurisdiction. We seem to have a tendency every time somebody doesn't like a decision of the Tribunal to immediately say, gee, now shouldn't they do something less? [Stanley Wong, Davis & Company, 65:09:15]

When it comes to the question of procedural protection, there cannot be said to be any definitive answer to the question: "how much is enough"? As a general rule, the "higher the stakes" for the parties, the higher the degree of procedural protection to which they should be entitled.

The Tribunal, like any court, should have the flexibility to manage its docket as it sees fit. That is what the Tribunal has at this point, albeit there seems to be an ever-increasing desire to put fixed time limits around various activities in the pre-litigation phase. But that discretion to determine the appropriate balance between expedition and fairness should be left with the Tribunal going forward. [John Rook, Osler, Hoskin & Harcourt, 65:09:45]

For example, proceedings which could lead to jail time would attract the highest degree of procedural fairness (that of a criminal court, with the criminal procedures, rules of evidence and a "beyond a reasonable doubt" burden of proof). At the other end of the continuum, small civil matters (such as licensing decisions) would warrant a lesser degree of procedural protection. However, "small stakes" for a large firm may, in fact, be very "large stakes" for a small firm. For that reason, procedural protections must also address the concerns of small business.

Questions of "how much fairness is enough?" seldom admit easy answers. As an example, it would seem reasonable to suggest that a person is entitled to be put on notice if a legal proceeding is commenced against him. It offends our sense of justice to think that a court proceeding could take place — and an order made against a person — without that person having any notice or chance to respond. Indeed, the right to notice is an important principle often reiterated by civil courts. For that reason, courts generally permit applications without notice (*ex parte*) only in exceptional circumstances.

The difficulty is if we insist too much on this full due process system, which takes tremendous time, and for which we have this judicial model … [S]ometimes you wonder, is this process really designed to get to the truth? If we could solve that side of things, that would go a long way to dealing with questions of independence and so forth. [Margaret Sanderson, Charles River Associates 59:12:00]

But when we pursue the idea of the "right to notice" a little further, it becomes less clear. First, giving "notice" of a proceeding is meaningless if the person being put on notice (the respondent) can do nothing to influence the outcome of the proceeding. For the notice right to have any kind of meaning or purpose, there must at least be some opportunity to affect the outcome of the proceeding. This is done by permitting the respondent to challenge the evidence upon which the applicant seeks to rely. But to do that, the defendant will need to have some way of "discovering" the applicant's case, and so the discovery process becomes necessary. And what will be done if one party refuses to disclose the information the other requests? There must be some way to compel the parties to disclose their documentary evidence. Also, there must be a procedure in place to allow the parties to settle disputes over the proper procedures to apply in a proceeding. This is done by way of motions. Each of these motions must be properly resolved on their merits. Furthermore, the respondent should be given the opportunity to present evidence on his own behalf, and this will likely involve hiring expert witnesses. In this way, the simple right to notice may develop into an extensive set of procedural and substantive entitlements. The adversarial

process produces results that are consistently fair and just, but frequently at very high cost.

Out of consideration for principles of procedural fairness, the Tribunal aims to provide more, rather than fewer, procedural protections. This means that parties are generally given the time they need to complete the proceeding "in the fullness of time," without strong direction from the Tribunal. As well, parties will often agree to timetables for dealing with cases, production of documents, etc., and these time frames may be quite lengthy in complicated cases.

Case management also means limiting witnesses. You might be interested to know that in the Microsoft case … they had only 24 witnesses and the decision was 46 pages long. The Superior Propane case that you've heard about a lot had 91 witnesses and a 109-page decision. I think, frankly, that's reflective of something short of aggressive case management. [George Addy, Osler, Hoskin & Harcourt, 59:11:35]

Case Management

The Committee shares the concerns of those who complain that Tribunal proceedings are long and expensive. Commentators focused on several areas where procedures could be improved:

- the time in which the steps in the proceeding must be completed;
- the time allocated for, and the scope of, examinations for discovery; and/or
- the amount of expert evidence the parties may adduce.

The Tribunal currently has authority, under section 16 of the *Competition Tribunal Act*, to make general rules (subject to the approval of the Governor in Council) regulating the Tribunal's practice and procedure. Those rules currently exist in the *Competition Tribunal Rules*,[11] which set out a complete code of procedure for the adjudication of disputes before the Tribunal, including the substantive steps the parties must complete and the time within which the steps must be completed. The steps in the proceeding include the exchange of pleadings, discovery, the pre-hearing conference, granting of interim relief, applications by interveners, interlocutory motions and the hearing itself.

Frankly, many of my colleagues … fought tooth and nail, saying, "Well, that's not justice. Justice means you can have as many witnesses as you want, you can plead as long as you want, and you can get whatever adjournments you want." I think the hesitancy on the part of the Tribunal to do more is because there's this view of a private bar to say the model is like court. [Stanley Wong, Davis & Company, 59:12:20]

11 SOR/94-290 as amended SOR/96-307; SOR/2000-198.

The Tribunal is aware of these criticisms and has made, and continues to make, constructive efforts to address them. Most notably, the Tribunal established a Tribunal-Bar Liaison Committee in 1997 comprised of Tribunal members, members of the Competition Law Section of the Canadian Bar Association and the General Counsel of the Department of Justice's Competition Law (who represents the Commissioner of Competition). The Liaison Committee reviews Tribunal procedures to determine how they might be refined and improved. At the time of drafting of this report, a number of procedural improvements are anticipated. One set of procedures will replace The current discovery process — traditionally the part of the process that takes the most time and results in the most interlocutory litigation — will be replaced with the following set of procedures:

The tendency is always to say, well, let's tinker with the Tribunal process rules, and hopefully that will solve the problem. That's not always the case. That can help, but there also has to be aggressive case management on the part of the Tribunal as well. By way of example, a recent case, one of the many involving Air Canada, was adjourned for six months without any reasons being given. [George Addy, Osler, Hoskin & Harcourt, 59:11:30

- a reciprocal obligation upon the parties to deliver a disclosure statement setting out a list of the records upon which they intend to rely at the hearing;
- "will say" statements of non-expert witnesses who will be appearing at the hearing;
- a concise statement of the economic theory in support of the application.

Moreover, the new procedures will permit certain information provided by the respondent to be read into evidence rather than having the witness testify.

Equally important, the new procedures will depart from the traditional model of permitting each party to adduce all of its expert evidence in turn. Instead, the Tribunal will group experts on a particular issue together in panels. Each expert will make a statement setting out his opinion, which will then be subject to cross-examination by the other experts, rather than by their lawyers. Counsel will still have the right to question experts in a limited manner. Apparently, this approach has been used in Australia with some success reported.

I would urge that the Tribunal continue to maintain a broad and flexible discretion to manage cases in both the parties' and the public interest. I am concerned about the attempt by the rules and by members of the Tribunal to think that this can be done by fixed rules, which mostly relate to the timing of when things should be filed and the like. In my judgment that is simply tinkering at the edges of substance. [John Rook, Osler, Hoskin & Harcourt, 65:10:45]

The Committee is also aware that the Tribunal-Bar Liaison Committee is preparing a discussion paper to explore the possibility of creating similar rules with respect to mergers. These amendments would relate to electronic filing and hearing, attempting to limit the number of witnesses to

be called at the hearing, and the introduction of time limits (four months or less from the date of filing of the notice of application) for the issuance of reasons and orders by the Tribunal. The new procedures are aimed not only at reducing the time for the matter to be resolved, but also to bring a greater degree of certainty to the proceedings, which will ultimately benefit the parties in conducting their affairs.

In my judgment, the Competition Tribunal is now managing its caseload very effectively, and recent litigation before the Tribunal evidences that. That's not to say that there won't be long cases in the future; indeed there will be. If there are, I don't believe this committee should engage in hand-wringing over that process. It's in the nature of litigation. [John Rook, Osler, Hoskin & Harcourt, 65:10:45]

The Committee commends the Tribunal for its timely and thoughtful reforms, and encourages it to continue the process. However, the Committee cautions that any contemplated limits on the right of a party to present its case fully and fairly must always be approached with special consideration for established principles of fairness and justice. Restricting the number of witnesses that a party may call, for example, or the amount of time within which the party must complete their submissions, always runs the risk of creating the reality or appearance of injustice.

The Committee has assessed several possible options to address the issue of perceived shortcomings in Tribunal proceedings. We could, for example, recommend that the government amend the *Competition Tribunal Act* to impose procedural limits on Tribunal proceedings; or we could recommend that the government amend the Act in order to require the Tribunal itself to change its rules to create limits on its proceedings.

[Y]ou have to be able to say to the parties, "I want experts on this issue and this issue, and you'd better file experts in this area," instead of saying, "You do what you want, you do what you want, and then you can reply and you can reply." That is not case management in this area. This is one where you have to be extremely aggressive, running the case from the first day it comes into the Tribunal. The Tribunal can do that without amendment to the process. Every time you have amendment, it leads to more jurisprudence about what it really means. The framework is good enough for the Tribunal to make these changes. [Stanley Wong, Davis & Company, 59:12:20]

The Committee, however, believes the first option is problematic for several reasons. The Committee has no direct experience with, and no particular expertise in, the conduct of Tribunal proceedings. Furthermore, the *Competition Tribunal Act* clearly anticipates that Parliament originally intended for the Tribunal to determine its own procedures, and it appears to be actively engaged in doing so. For these reasons, the Committee does not find that there is a compelling reason to depart from this model.

The second option would impose an obligation on the Tribunal to make rule changes, but would leave the consideration of how exactly to do so in the hands of the Tribunal. Again, however, it is clear that the Tribunal already has the necessary authority under its statute to

impose case management procedure, and is actively considering ways of doing so.

[A]s we strengthen the Tribunal process and improve the adjudication mechanism through the Tribunal, we should not at the same time give the Commissioner powers to avoid the Tribunal. I think the interim injunction provisions that have been granted to the Commissioner in the context of airlines are a special case, but if one wants to have separation of investigation and adjudication, one should have a revitalized Tribunal. It doesn't help to give, at the same time, the Commissioner powers whereby he can avoid the Tribunal. [Margaret Sanderson, Charles River Associates, 59:12:30]

Ultimately, the Committee believes that the Tribunal is in the best position to enunciate the rules governing its procedures. For that reason, the Committee recommends:

7. **That the Competition Tribunal, in consultation with the Tribunal-Bar Liaison Committee, continue its ongoing review of procedures with the aim of creating an adjudicative system that will ensure "just results" in an expeditious and timely manner. Such procedures should aim at reducing parties' costs, as well as the time required, in bringing contested cases to a conclusion while, at the same time, continuing to ensure that due consideration is given to principles of procedural fairness and the appearance of justice.**

Balancing the Incentives:
Damages, Court Costs and Fines

I believe that administrative penalties and damages are something that are necessary to make our Act effective. Currently, abuse of dominance is a provision that can be read this way: do it until you're told not to. And what's the cost of that? The advice we have to give is that it's not unlawful until the tribunal says so. Of course, the clients can potentially read into that, do it until they say no. [Robert Russell, Borden, Ladner & Gervais, 65:09:35]

The relief available to a prospective applicant is a critical factor in determining whether to proceed with a case to the Tribunal. Although, with the adoption of Bill C-23, the right to bring a private action before the Tribunal will exist in a limited sense, the incentives contained in Bill C-23 are clearly designed more to discourage than to encourage the applicant to commence private proceedings. The absence of any remedy of damages is the most obvious incentive against litigating cases. Denying the plaintiff what would be, in most civil cases, the most important available remedy might reasonably be expected to have an impact on the decision of whether or not to start an application, i.e., is the remedy (an order) worth the time, effort and expense? The possibility of damages awards is also an important deterrent to anticompetitive behaviour. Currently, the only relief available to the applicant is a cease and desist order of the Tribunal, or in some cases, an order for divestiture. But there is no right to sue for damages.

The right to sue for damages is a fundamental right accorded to plaintiffs in civil proceedings throughout the world. It is an injustice that applicants in Tribunal proceedings should be denied the same fundamental right as any other litigant to claim restitution for the losses they have sustained as a result of another person's anticompetitive conduct. The ostensible reason for the policy is that providing a damages remedy would lead to a rash of litigation, as has been the case in the United States and that this, in turn, would cause business to leave Canada, oppressed by the high cost of defending vexatious lawsuits.

But unless we have significant penalties, we have no teeth in these provisions. We simply litigate, and litigation can be a tool in itself to draw things out until the damage is done, until the competitor disappears from the landscape. Only with the threat of significant penalties with these sorts of provisions will we have true deterrents in our economy. [Robert Russell, Borden, Ladner & Gervais, 65:09:35]

The Committee is fully aware of the many differences that exist between the Canadian and U.S. approaches to antitrust enforcement, and we are of the view that the differences are so fundamental that no meaningful comparison can be drawn between the two. In addition to permitting treble damages to the successful plaintiff, the U.S. approach also contains other incentives to encourage litigation including, for example, civil jury trials and costs awards that overwhelmingly favour the plaintiff. For that reason, the Committee is firmly of the view that there is no merit to the argument that creating a right of damages in Tribunal proceedings would have an adverse impact on the business environment. In fact, quite the opposite could occur. Creating a fair system in which all persons and enterprises are able to protect their rights and economic interests would tend to attract investment, not drive it away. This conclusion is supported by the United States experience where, despite having the most litigious antitrust regime in the world, investment still flocks to the business environment of the United States ahead of any other in the world.

[A]dministrative penalties and damages to parties that are harmed. Without that, we don't have teeth in this legislation for important reviewable matters. If you put a company out of business today, all that will be said to you is, you shouldn't have done it. That's not a good enough deterrent. If you're going to abuse your dominant position in this country, you should be called to pay for damages to the party, costs for the proceedings, and penalties because the public interest has been affected. We need those teeth. [Robert Russell, Borden, Ladner & Gervais, 65:10:45]

Moreover, the argument is not borne out by the experience of ordinary civil courts in Canada. Our courts routinely assess and awards damages in civil cases, and there is absolutely nothing to suggest that the availability of the remedy has led to a rash of strategic litigation in those venues. For the same reason, there is nothing to support the position that permitting applicants to claim for damages before the Tribunal would result in a significant increase in litigation, particularly if the relief is limited to "single damages," i.e., the actual provable loss. The threat of strategic litigation would also be kept in check by the

Tribunal's new cost rules, as well as its power of summary dismissal and to refuse leave to commence an application.

As we note from the area of hard-core cartels, even a $10 million fine may not suffice. I know when I was at the Competition Bureau, when we were looking at a particular case, we calculated the overcharge to be hundreds of millions of dollars, so even a $10 million fine in that particular case, had it gone forward, would have been a mere fraction of the profits. If you're going to introduce an administrative monetary penalty for abusive dominance, I think you really want to give the Tribunal the greatest flexibility by allowing it to impose a penalty at its discretion. That will enable it to set the penalty at any level. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 65:10:55]

The Tribunal is composed of very experienced members of the judiciary and experts in economics, who certainly have the necessary expertise to assess damages. The Committee does not recommend under any circumstances the consideration of treble damages, such as are available to litigants in the United States, and which is said to have led to the growth of a massive antitrust litigation industry in that country.

Until claims for damages are permitted under the *Competition Act*, it is likely that the balance of litigation incentives in the Act will remain less than optimal. Some good cases likely will not be brought given no possibility of recovering damages. These would-be applicants will simply decide that the limited injunctive relief available from the Tribunal is just not worth the high cost of pursuing a case to hearing. Accordingly, from the perspective of the applicant, there is a good argument to be made for creating a right to sue for damages.

Historically, Canada's antitrust legislation has been principally concerned with the public interest in competition as opposed to the private interests of individual competitors. If you amended the legislation … to afford a litigant the right to damages, I think the implications would be quite profound … I think inevitably where you would end up is that the Tribunal would become a court like any other, only it would be a specialized court. So a lot of thought has to be given on whether it is in the public interest to migrate the legislation in that direction. [John Rook, Osler, Hoskin & Harcourt, 65:10:55]

Moreover, damages would provide excellent deterrence. The possibility of being liable for damages would certainly provide additional incentive for dominant firms to refrain from anticompetitive practices by raising the potential cost of embarking on such a course. Increasing compliance with the Act would, of course, also relieve the Canadian taxpayer of some of the expense of having the Bureau solely responsible for enforcing the Act. Currently, there is little disincentive to a dominant player from abusing its market power. The abusive firm knows that the worst that will happen is that, at the end of the proceeding, it will be ordered merely to cease and desist the anticompetitive behaviour, and perhaps to pay a portion of the applicant's legal costs. It will not be required to pay damages, no matter how much its victim or victims may have lost. Compare this, on the other hand, to the enormous profits that the abusive firm may realize while the case is before the Tribunal. The absence of damages creates a very strong incentive for the abusive firm to prolong the litigation; doing so will, of course, raise its legal costs somewhat, but it will not increase its exposure in the much larger area of damages. In the meantime, the victim of the conduct will continue to suffer losses (and will thus be under increasing pressure to settle

the case), while the abusive firm will continue to realize its ill-gotten gains, without any concern of ultimately having to pay damages to its victim.

With the adoption of Bill C-23, the Tribunal will now have the authority to award court costs to a successful litigant. This is also expected to have an impact on the prospective applicant's decision of whether to take a case to the Tribunal, although it cannot be said to be a strong incentive either way. The spectre of having to pay a successful defendant's cost would tend to deter an applicant not strongly convinced of the merits of his case, certainly as much as the prospect of recovering costs would tend to encourage it. Furthermore, at least some cases, it is anticipated, will not obtain the leave of the Tribunal required to bring an application under sections 75 and 77, which is another possible disincentive to commencing an application.

I think some real benefit can be derived from looking at other case management models where a judge is assigned not only to schedule, but to manage what issues are coming forward before theTribunal. We have, I believe, a very good example in the commercial list in Toronto....There are judges, typically six at a time, who are assigned to the list — three fairly permanent members, and three members who are rotated in every six months. It has a specific protocol in dealing with commercial litigation, and a very tight case management system, where a judge not only manages all of the pre-trial hearings, if you will, but also enforces that the parties go through methods of mediation, typically before they get to a trial. ... Effective case management by a judge *... is something that would, I believe, definitely assist our procedures in terms of the Tribunal.* [Robert Russell, Borden, Ladner & Gervais, 65:09:25]

The Committee also found considerable support among witnesses for giving the Tribunal the authority to levy administrative monetary fines as a further deterrent to egregious anticompetitive conduct. Although the threat of damages is certainly an effective deterrent, fines would be a useful additional remedy in situations where: (1) an award of damages would not, in itself, be a sufficient deterrent; (2) the victims of the conduct could not be easily ascertained, for example, where the loss has been shared by a large number of consumers; or (3) where the losses of each is too minimal to make a damages award a practical remedy.

I think there is a need to review the whole scheme as to what we're trying to do … [I]n Bill C-23 there's now a penalty of $15 million in the airline situation. I think that's too hasty. I appreciate there are all sorts of political considerations, but … you need to look more generally at what principles you want enshrined in the act to deal with reviewable matters. … [I]t's not a question of what we can do to stop the big business. When you have these penalties in place, they will apply equally to smaller businesses. [Stanley Wong, Davis & Company, 65:10:15]

Administrative penalties, in order to have any effect, would have to be large enough to deter anticompetitive behaviour. In fact, to deter the conduct in the future, the penalty must be greater than the profit that the abusive firm might realize as a result of its anticompetitive conduct. For that reason, there should be no ceiling placed on the size of the potential fine that the Tribunal might levy. The size of the fine should be left to the discretion of the Tribunal, having regards to the profits realized by the abusive party and such other factors as it considers correct in the circumstances of the case.

When … we take a holistic approach and think about the institutional structures and the incentives that are put in place … that will go a long way towards dealing with some of these cost concerns. [Margaret Sanderson, Charles River Associates, 59:11:25]

Accordingly, the Act must provide the optimum mix of incentives to promote compliance with the Act and to encourage meritorious cases to come forward. The Committee was presented with two options:

1. That the Government amend the *Competition Act* to permit the Tribunal, in addition to the other remedies available to it in civil proceedings, to order the compensation to a party in the form of a damages award, and to levy administrative monetary penalties under section 79 as a deterrent to anticompetitive behaviour and the just and expeditious resolution of Tribunal proceedings.

Parliament should ask itself, how much of the public resources we have to allocate amongst many valuable objectives can we afford to put into this kind of adjudication? [Jack Quinn, Blake, Castles & Graydon, 59:12:30]

2. To wait and see the impact of Bill C-23 reforms (i.e., private access, hearing of references) on the operation of the Tribunal and its procedures.

It is not clear whether the creation of the new right of private access, as well as the Bureau's new procedures to hear references and to summarily dismiss applications, will actually achieve the desired objective of encouraging positive litigation. The Committee is not convinced that these narrow reforms will, in themselves, strike the right balance. For this reason, the Committee recommends:

We just have to open up to the possibility of allowing private actions, possibly including damages or at least cost awards for some of these other offences. [Tom Ross, University of British Columbia, 59:12:45]

8. That the Government of Canada amend the *Competition Act* and the *Competition Tribunal Act* to extend the private right of action in the case of abuse of dominant position (section 79) and to permit the Competition Tribunal to award damages in private action proceedings (sections 75, 77 and 79).

Jurisprudence — Bringing Cases

[W]e should be focused on … what are the right, economically sound designs of the law, and the jurisprudence should follow. [Neil Campbell, McMillan Binch 59:12:15]

There was a broad consensus among witnesses that simply not enough cases are being brought to the Tribunal. This is not to suggest that litigating disputes is to be encouraged for its own sake; however, bringing cases to the Tribunal will lead, over time, to the development of judicial interpretation that will ultimately serve to clarify the meaning of, as well as improve compliance with and enforcement of, the Act. The challenge for lawmakers is to create a system in which good cases (i.e., cases with merit) may be brought.

At the same time, we must be careful that we do not encourage frivolous, vexatious or strategic litigation.

Why would one bring an application to the Tribunal as a private litigant if you can convince the Commissioner to make an ex parte *application to stop your competitor from doing what it is doing in the marketplace? Why spend your money when you can spend the money of the public …?* [John Rook, Osler, Hoskin & Harcourt, 65:09:45]

The Committee is satisfied that the new Tribunal powers created by Bill C-23 are well designed to discourage frivolous litigation. However, whether the reforms will function to encourage good cases to come forward is far from clear.

Many disputes will undoubtedly be resolved by the Tribunal's new power to hear references.[12] At the same time, it is reasonable to anticipate that some cases will be dealt with summarily under the Tribunal's new powers of summary judgment. Cases obviously devoid of merit will be "stopped at the gate" by the Tribunal's right to deny leave to commence the application.

Parliament has surrounded this right of public access with a number of fences … and it remains to be seen whether it's practicable and will be used. … [I] don't see the incentives there particularly for a private litigant to proceed … [John Rook, Osler, Hoskin & Harcourt, 65:10:45]

The Committee expects that the new right of private access to adjudicate disputes under sections 75 and 77, created by Bill C-23, will add to the Tribunal's caseload, as private individuals look to the Tribunal for protection from anticompetitive business practices. However, owing to the non-availability of any remedy in damages, the Committee does not anticipate the flood of litigation that some opponents of private access have predicted. Still it is anticipated — indeed, hoped — that stakeholders will use the legislation in good faith to assert their rights before the Tribunal and protect their civil rights and, more generally, to protect healthy competition.

We all benefit from having a reasoned decision. Not only will the complainant benefit, members of the public will benefit by understanding the way the Bureau is applying the law in a particular situation. You get an accountability benefit from seeing what the Bureau has done or has not done. [Neil Campbell, McMillan Binch 59:11:25]

On the subject of references, the Committee heard several criticisms of Bill C-23. That bill contemplates that the Commissioner alone, or both parties if they agree, may direct a reference to the Tribunal on a question of law, mixed law and fact, jurisdiction, practice or procedure. The Commissioner may, of his own accord, refer these matters (except for a question of mixed law and fact), but a responding party may not. The Committee does not find

12 The Tribunal will be able to hear references on questions of law, mixed law and fact, jurisdiction, practice or procedure in relation to the application or interpretation of Part VII.1 (*Deceptive Marketing Practices*) or Part VIII (*Matters Reviewable by the Tribunal*), whether or not an application has been made under those sections. Similarly, the Commissioner may, of his own accord, refer a question of law, jurisdiction, practice or procedure (but not of mixed law and fact) in relation to the application or interpretation of Part VII.1, VIII or IX (notifiable transactions, i.e., mergers).

In private litigation, the parties have the freedom to spend as much money on their cases as they think their interests bear, so there's a natural competition in spending money on cases. Part of the resistance to the bureau bringing more cases has been the amount of money they consume. This is simply saying that the process becomes a kind of pearl without price. [Jack Quinn, Blake, Castles & Graydon, 59:12:30]

any compelling policy justification for this apparent inequity and the Committee, therefore, recommends:

9. That the Government of Canada amend section 124.2 of the *Competition Act* to permit a party to a contested proceeding under Part VII.1 or VIII to refer to the Tribunal a question of law, jurisdiction, practice or procedure in relation to the application or interpretation of Part VII.1 or VIII.

Tribunal Resources

I think there is a general support for the idea that Tribunal proceedings should start and finish in six months, including a four-month period for adjudication and two months to write the decision. My sense is that the Tribunal itself is predisposed to pursue that and obviously requires the cooperation of the parties as well as sufficient resources. I understand one of the problems with delay in the past has been that there have been insufficient judicial resources. [Stanley Wong, Davis & Company, 65:09:25]

The Committee heard little evidence on the adequacy of the Tribunal's resources. However, some witnesses did point to a shortage of economist members in some cases, and this has reportedly resulted in occasional delays in cases proceeding in a timely fashion. We anticipate that the Tribunal's current budget may need to be increased in order to deal with cases brought by private parties after the adoption of Bill C-23. How many new cases will result remains to be seen. At the same time, it is possible that the power to grant summary judgment and to hear references may result in a greater number of cases being resolved short of a full-blown hearing, and this may result in some saving of resources.

I do not think just throwing more money there will solve the problem. If we kept the model we have today … you can have a situation such as the Superior Propane case where the Commissioner can lead ten economists as experts. … I think we have to change this process, or the quantity of resources that will have to be devoted to it … [W]hat the general taxpayer would view is a reasonable allocation, given competing and highly desirable goals for government policy. [Margaret Sanderson, Charles River Associates, 59:12:35]

In any case, the Committee is of the view that the Tribunal itself is in the best position to determine its resource requirements and that the current budgetary process provides the means to address this issue. For this reason, the Committee does not feel the necessity to comment on the adequacy of the Tribunal's current budget. The Committee intends to monitor the operation of the Tribunal as part of our oversight of the operation of Canada's competition law framework.

The *Competition Tribunal Act*

The Committee heard that subsection 12(1) of the Act, as it is written, does not reflect current Tribunal practice. That section states that questions of law shall be determined

only by the judicial members, while questions of fact or mixed law and fact shall be determined by both judicial and lay members.

Distinguishing questions of law from questions of fact or mixed fact and law often presents difficulties, particularly in a statutory regime that is driven by market forces. The Tribunal, in its practice, does not preclude lay members from expressing opinions on questions of law. In one case, in fact, the appeal court affirmed the dissenting opinion of a lay member on an issue of the Tribunal's jurisdiction.

One area that in my judgment would add a lot of accountability, particularly in merger cases, is if a merger is before the Tribunal the reference power that exists in Bill C-23 should be amended to permit the respondent to bring an application to the Tribunal for a ruling on a summary point … If the respondent … had the power to go to the Tribunal and say, "this is wrong, this is outside the mandate of the Commissioner in these circumstances, and you ought to do something about it", that would have a very healthy disciplinary effect on the exercise of discretion … [John Rook, Osler, Hoskin & Harcourt, 65:10:45]

The Committee believes that there is no compelling reason to maintain the artificial and somewhat unwieldy distinction between questions of fact and question of law or mixed fact and law in Tribunal proceedings. Accordingly, the Committee recommends:

10. That the Government of Canada amend section 12 of the *Competition Tribunal Act* to permit questions of law to be considered by all the members sitting in a proceeding.

Automatic Right of Appeal

Section 13 of the *Competition Tribunal Act* creates an automatic right of appeal[13] from any decision or order of the Tribunal, including interim (temporary) orders.[14] One exception exists to this automatic right of appeal: an appeal on a question of fact alone may only be brought with leave (permission) of the Court. This approach reflects a principle known as judicial deference. It is based on the notion that the Tribunal, with its specialized expertise and full hearing of the evidence, is in a better position than the appeal court to determine evidence-based findings of fact. But should the idea of deference extend to questions of law as well?

Judicial members have the exclusive right to decide on questions of law and then all other questions decided by the entire panel. … [I]t's a bit awkward for the Tribunal to operate in that way … in reality the Tribunal members probably look at everything together [Stanley Wong, Davis & Company, 65:09:15]

13 To the Federal Court of Appeal.

14 However, section 103.3 interim orders (created by Bill C-23) would not be reviewable.

Right now there is an automatic right of leave to appeal except on questions of fact. I know of no skillful lawyer who can't at least make a question of mixed fact and law to launch an appeal. This, I think, unnecessarily delays the adjudicative process, given that the purpose of the Tribunal is to be a specialized Tribunal. [Stanley Wong, Davis & Company, 65:09:15]

Judicial members of the Tribunal are judges of the Federal Court. It is evident to the Committee that, with such a depth of legal knowledge and experience, the Tribunal warrants a very high degree of deference on matters of law. Moreover, it has been clearly shown that lay members of the Tribunal can, and do, comment meaningfully on issues of law in Tribunal decisions. For this reason, the Committee believes that the principle of deference should extend to the Tribunal not only in questions of fact alone, but equally in questions of law of general application and laws specific to competition proceedings.

It is important to be clear that requiring a party to obtain leave to appeal does not deprive the party of its right to appeal. It simply requires that the appellant first convince the Court of Appeal that there is sufficient merit to the appeal to warrant a hearing. The Court of Appeal might, if it finds no merit in the appeal, summarily dismiss it without the necessity of going through a full appeal proceeding. In this way, many proceedings might be abbreviated without sacrificing principles of procedural fairness. Accordingly, the Committee recommends:

It is not good for the system to have a very prolonged period for adjudication of appeal and subsequent appeal because, certainly in the merger context, very few mergers will be held up. That is, mergers that were not completed would not wait. [Stanley Wong, Davis & Company, 65:09:15]

11. That the Government of Canada amend section 13 of the *Competition Tribunal Act* to require that an appeal from any order or decision of the Tribunal may only be brought with leave of the Federal Court of Appeal.

CHAPTER 4: CONSPIRACIES AND OTHER HORIZONTAL AGREEMENTS

The Organizational Continuum

Cooperation among competitors is a double-edged sword. On one hand, it may offer prospects of economic benefits; on the other hand, it may bear the costs of dulled competitive performance. The economic benefits develop from the synergistic effects when individuals and organizations with different competencies and resources are brought together. More specifically, such collaboration may: (1) result in new and less costly production processes; (2) facilitate the attainment of scale and scope economies; and/or (3) lead to a more efficient allocation of resources or improved product quality. A typical example in today's knowledge-based economy would be the combining of research, development and marketing resources of two or more firms to reduce the time needed — as well as risk exposure — to develop and bring new products to market. An additional social benefit would be the elimination or mitigation of duplicative work and facilities. Unfortunately, sometimes these benefits accrue, in part, to a market sharing or a coordinated pricing agreement needed to make such cooperation profitable. This may lead to, in varying measure, restricted supply, higher prices, less product selection and/or less-than-optimal product quality. Hence, an intricate weighing of economic factors is required to offer a definitive conclusion on the ultimate impact of such cooperation.

In many cases, a strategic alliance is just a contractual joint arrangement similar to a merger. It may be dictated by tax considerations rather than any particular overriding purpose in having a contractual arrangement. [Tim Kennish, Osler, Hoskin & Harcourt, 59:09:25]

It's also reasonable to think about these arrangements between firms that fall short of mergers but are not hard-core cartel behaviour, like many strategic alliances and joint ventures. There's … [the] example of a joint venture to develop a vaccine. A lot of these arrangements are wonderfully efficient on the one hand, but pose some certain competition challenges on the other. They need a more sensitive, nuanced evaluation of the sort we give to mergers. [Tom Ross, University of British Columbia, 59:09:30]

At the outset, one should be aware that such cooperation could take several organizational forms. It can be purely contractual, purely combinational, or it can be located anywhere between these polar opposites. The Committee will, for simplicity, include the diverse set of business relationships on this organizational continuum

under the term "strategic alliance."[15] This integration can be contrasted with that of a merger or acquisition of assets or capabilities.

There are many agreements that incidentally affect prices or incidentally affect customers but are not in essence price-fixing agreements. If you stick to prohibiting agreements to fix prices, i.e., agreements the object of which is to fix prices, as opposed to agreements that simply affect prices as an ancillary matter, you'll get much closer to truly hard-core criminal behaviour. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:12:25]

Public concern over cooperation among competitors, when it is simply a veil for a cartel, begins to rise not only because it potentially redistributes income (from buyers to sellers) in a covert way that is tantamount to fraud, but it may also reduce economic efficiency as resources are misallocated in the economy. Indeed, such monopolization results in lower economic welfare and is, therefore, deemed to be a crime against society. However, a thorough competitive effects review would ensure that both types of cooperation, whether a merger or strategic alliance, receive similar treatment because neither can a priori be categorized as pro-competitive or anticompetitive.

Theoretically, a strategic alliance that is not what competition specialists call a "naked hard-core cartel" may be afforded criminal or civil treatment under Canada's *Competition Act*, even though it may be strictly pro-competitive and restrict competition only in an ancillary way. Law enforcement may proceed by way of a criminal trial under the conspiracy provision (section 45) or by way of a civil review under either joint dominance (section 79) or a merger (section 92). Uncertainty abounds on the possible course to be taken, but a strategic alliance would meet the public policy ideal of a "level playing field" with respect to that of a merger only if it received a section 92 through 96 review. Unfortunately, as many witnesses told the Committee, a strategic alliance may be inadvertently swept into section-45 treatment, where criminal law is not well suited to judge it. Specific court deficiencies in a section 45 case are:

It's somewhat odd that if two firms or competitors get together in a merger, they get a civil review where they get to talk about efficiencies, and there's a kind of cost-benefit evaluation of the proposal, yet if they do something less than a merger, they're subject only to criminal law, and people can go to jail and pay fines. [Tom Ross, University of British Columbia, 59:09:25]

- the absence of specialized expertise in the criminal courts;
- the tendency of structural considerations (market share or concentration) to dominate the very limited analysis;

15 In the past few decades, the business sector has preferred the strategic alliance, which usually takes the form of a joint venture, to that of a full-blown merger because this form involves fewer financial trappings associated with increasing integration. These horizontal agreements typically provide for formal supply arrangements, access to technologies and specialized expertise, distributional channels and customers (particularly in foreign markets where there are trade barriers), capital funding, risk sharing, and/or collaboration on research and development.

- the lack of consideration given efficiencies or innovation; and
- the limitation of sanctions to fines, in the absence of behavioural solutions.

I don't think the strategic alliance bulletin provided the comfort the business community was looking for, because it was very evident that there is an overlapping potential application of not only the merger provisions but also the criminal provisions of section 45 … and even joint dominance provisions. [Tim Kennish, Osler, Hoskin & Harcourt, 59:10:20]

A "chilling effect" on pro-competitive strategic alliances results, and the Committee intends to provide a solution to this design flaw. However, before doing so, the Committee will review and address the circumstances that have led to the over-inclusiveness and under-inclusiveness of the conspiracy provision.

History of the Legal Treatment of Conspiracies

The prohibition against horizontal agreements (i.e., between competitors in the same product market) to fix prices, allocate markets and/or restrict the entry of competitors has been a central feature of Canada's antitrust Act since 1889. However, for most of the original Act's history, the prohibition was ineffective due to the presence of the word "unlawful" and the lack of a permanent investigative and enforcement body. Between the *Combines Investigation Act* of 1923 and the enactment of the *Competition Act* in 1986, the enforcement of the prohibition varied according to the legal interpretation given to the term "unduly" in the provision's reference to "prevent or lessen competition unduly" when assessing the agreement's economic effects. In this period, several unsuccessful attempts were made to rid the Act of this word in order to strengthen the prohibition. After the Supreme Court decisions in *Aetna Insurance* (1977) and *Atlantic Sugar* (1980), the Crown had to prove that the alleged conspirators both intended to enter into the agreement and intended to lessen competition "unduly." The double intent proved hard to establish, as can be seen by the drop in the Crown's success rate from 90% to 55%.[16]

We have not had great success with this provision. Particularly because of some of the burdens and the wording of the section, it's made it much more difficult to use it against hard-core cartels … [Robert Russell, Borden, Ladner & Gervais, 59:09:10]

However, the enactment of the *Competition Act* de facto reversed these court decisions. Section 45 of the *Competition Act* provides that "everyone who conspires, combines, agrees or arranges" to lessen or prevent competition "unduly" is guilty of a criminal offence and is

[T]he $150 million in fines recently collected is the coattail argument. We have collected $150 million in fines in Canada after other jurisdictions have enforced against those international cartels. We've done very well at getting guilty pleas on them, but I don't consider that to be a success of our statute. [Robert Russell, Borden, Ladner & Gervais, 59:09:40]

16 William Stanbury, "The New Competition Act and Competition Tribunal Act: Not With A Bang, But A Whimper," *Canadian Business Law Journal*, Vol. 12, 1986/87, p. 20.

liable to fines and/or imprisonment. This provision incorporates a defence for horizontal agreements between competitors for:

[W]hen we analysed the cases back in the early 1980s, … we found that the government lost as many if not more of the cases because they couldn't prove agreement. It wasn't that they couldn't prove undueness; they couldn't prove there was actually an agreement. That is the cornerstone of a conspiracy section. [Lawson Hunter, Stikeman Elliott, 59:09:25]

- the exchange of statistics, defining product standards, or the sizes or shapes of product containers and packaging;
- the exchange of credit information, research and development, placing restrictions on advertising, promotion or measures to protect the environment; and
- the adoption of the metric system of weights and measures.

There are also specific defences for export consortia and specialized agreements.

The Act's most significant changes, however, were introduced in subsections 45(2.1) and 45(2.2). These provisions permit the Court to infer the existence of a conspiracy, combination, agreement or arrangement from circumstantial evidence; and while it is necessary to prove that the parties intended to and did enter into the agreement, it is not necessary to prove that the agreement was intended to have the effect of lessening competition "unduly." Subsequent jurisprudence has been consistent with this interpretation.

The question of whether to strike unduly from section 45 rather than go to a two-track approach has been raised before. The simple response to why we wouldn't do it is because it would make the section too inclusive. It would trap many agreements, which are innocent. For example, agreements between a franchise and a franchisee might be captured by section 45 if it simply said that any agreement that restricts competition, supply, production and so on. … [R.W. McCrone, Competition Bureau, 64:09:15]

The Supreme Court further provided the more controversial interpretation on the meaning and implications of the word "unduly" when it handed down its decision in the *Nova Scotia Pharmaceutical Association* case, which is commonly referred to as the *PANS* case. The courts are now required to conduct a two-part test on price-fixing arrangements before condemning them as lessening competition "unduly." The first part would be a market power test, while the second would be a test to establish injurious behaviour to competition that would qualify as "undue." This legal framework in fact establishes a partial rule of reason because agreements are neither treated as per se illegal, even those that are patently "naked hard-core cartels" with no redeeming benefits to society, nor treated under a "rule of reason," whereby the economic advantages and disadvantages of the agreement would be weighed. A strategic alliance that

restricts price competition only in an ancillary way would then be subject to less than a thorough review to determine its ultimate economic impact.

As it currently stands, the Crown must establish four elements beyond a reasonable doubt when bringing forth a section 45 case:

1. The existence of a conspiracy, combination, agreement or arrangement to which the accused is a party.

2. The conspiracy, combination, agreement or arrangement, if implemented, would likely prevent or lessen competition unduly (i.e., it does not have to be implemented);

3. The accused had the subjective intent of the first two elements; and

4. The accused was aware, or ought to have been aware, that the effect of the agreement would prevent or lessen competition *unduly*.

A review of the enforceability of the law on conspiracies is revealing.

I participated in a special council for the Attorney General of Canada in the Nova Scotia pharmaceutical proceedings, where we tried to bring clarification in the submissions to the Supreme Court of Canada in the early 1990s to the meaning of "undueness" in order to give broader certainty to the public and to the Bureau. And my own view today is that despite all those good intentions, section 45 really does warrant priority consideration. The reasons are … [i]t is both under- and over-inclusive. [Calvin Goldman, Davies, Ward & Beck, 59:09:20]

[Canada is] the only jurisdiction in the world that requires the level of analysis in order to prove a conviction under section 45. Most jurisdictions, … Europe, the United States, Australia, New Zealand, South Africa, … have adopted a per se approach to hard-core cartel behaviour, while providing for a civil track approach … to deal with strategic alliances … [Robert Russell, Borden, Ladner & Gervais, 59:09:10]

The Enforceability of Section 45

Competition law experts believe, almost unanimously, that section 45, as currently written, is hard to enforce in a contested trial setting, even when applied to a "naked hard-core cartel." They also believe the two-step "market structure-behaviour" tests provide too much room for litigating irrelevant economic matters in the case of a "naked hard-core cartel." Public enforcement costs are therefore excessive. Given that these views are so widely held, the Committee sees no reason for going to great lengths to validate them. The Committee will exclusively rely on Bureau data, analyses and conclusions.[17]

It's recognized that our standard of undueness is a partial rule of reason, but it doesn't embrace any recognition of efficiencies. Efficiencies are one of the objectives of competition law, and are something that ought to be considered in determining whether or not some action or arrangement ought to be condemned. [Tim Kennish, Osler, Hoskin & Harcourt, 59:09:25]

[17] Harry Chandler and Robert Jackson, *Beyond Merriment and Diversion: The Treatment of Conspiracies under Canada's Competition Act*, Competition Bureau, http://strategis.ic.gc.ca/SSG/ct01767e.html, May 2000. The Committee relies on the authors' assertion that none of the 51 cases constituted a pro-competitive strategic alliance.

[O]f the 22 contested cases, three were successful. Is every Department of Justice lawyer or those retained from the outside incompetent? No. The provision is a criminal standard. It requires, beyond a reasonable doubt, the proving of all the elements. That standard should be maintained. [Robert Russell, Borden, Ladner & Gervais, 59:09:35]

The Competition Bureau reports that 51 cases have been prosecuted under section 45 or its predecessor between 1980 and 2000. Almost 60% of these cases (29 of 51) resulted in a guilty plea. The conviction rate in contested trials was exceptionally low, somewhere between 10% and 15% (3 of 22). The Bureau estimates that slightly more than 35% of cases (6 of 17) were acquitted at trial or discharged at a preliminary hearing because of insufficient evidence of an agreement — the first element described above. Almost 65% of cases (11 of 17) were acquitted or discharged because of insufficient evidence of an undue lessening of competition (the second element) or of the parties' intent that the agreement would have that effect (the third and fourth elements). These data and analyses indicate that the burden of proof "beyond a reasonable doubt" is a formidable one, but the "undueness" element poses the greatest obstacle to a successful conviction under section 45.

[T]he Bureau contracted three independent studies [on the issue horizontal agreements amongst competitors]. … [T]hey all agree that hard-core cartel behaviour, such as price fixing, market sharing and output restrictions, should be a criminal offence without a competition test. [Gaston Jorré, Competition Bureau, 64:09:10]

The Two-Track Proposal: Criminal and Civil

At this point, the Committee must remind the reader that the object of competition policy is not about winning or losing litigated cases; it is about prescribing a framework for an efficient business sector that delivers products and services at competitive prices. We strongly believe that section 45 is meant to only apply to certain types of agreements, and the current law does not give fair warning of what type of agreement constitutes a serious indictable offence. Furthermore, although the Committee understands that writing law with so much precision as to preclude uncertainty is unattainable — watertight compartments are not possible — the law should not, at the same time, be written so loosely as to capture all horizontal agreements between competitors in achieving its objective.

There have certainly been prominent examples where the problem was evaluating the undueness of the lessening of competition. Clarifying this is the way to go, by breaking the law into two pieces — a criminal part without the word "undue" for naked price-fixing, hard-core cartels, and then a civil branch for the more complicated arrangements. [Tom Ross, University of British Columbia, 59:09:25]

As it currently stands, section 45 excessively relies on prosecutorial discretion, which can be exercised differently by different individuals, rather than on a law crafted to properly discriminate between the two forms of cooperation — an anticompetitive cartel arrangement and a competitively benign or pro-competitive strategic alliance. By the same token, the Committee does not think it is appropriate for criminal liability, which may involve fines and jail terms, to depend on a court's assessment of complex economic factors — such as the cross-price elasticity of

demand, the height of barriers to entry in the industry, the extent of sunk costs, the strength of other competitors or potential competitors, market power, etc. — that a court is not well suited to judge.

I don't see any basis for treating one type of horizontal arrangement, such as a merger, analytically differently from another type … such as strategic alliance. … So outside what would be the new criminal track under a revised two-track approach to conspiracies … you would … have … the same efficiency provision … [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:13:00]

Advocates for change have successfully persuaded this Committee to accept this view; in all respects, change is long overdue. The conspiracy provision of the *Competition Act* must be reformed to reflect modern business tendencies to form strategic alliances and joint ventures, circumstances in which the current Act is unnecessarily restrictive, while at the same time being under-restrictive in clearly anticompetitive cases. The Committee, therefore, recommends:

[Y]our interim report suggested if we go the two-track approach, the hard-core criminal per se provision might be limited to price-fixing and output restrictions. I would encourage you to expand that list to include market allocation — and by that I mean geographic market allocation and customer allocation — as well as certain types of group boycotts, such as group boycotts in support of price-fixing or keeping new entrants out of the market. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:12:45]

12. That the Government of Canada amend the *Competition Act* to create a two-track approach for agreements between competitors. The first track would retain the conspiracy provision (section 45) for agreements that are strictly devised to restrict competition directly through raising prices or indirectly through output restrictions or market sharing, such as customer or territorial assignments, as well as both group customer or supplier boycotts. The second track would deal with any other type of agreement between competitors in which restrictions on competition are ancillary to the agreement's main or broader purpose.

The Criminal Track

When we're going to go after hard-core cartel behaviour the standard should be met, but we shouldn't have to go into the economic effects. That's what every other regime in the world has done. Per se simply means if I engage in a price-fixing arrangement, you don't have to look to see whether it has an anti-competitive effect, with the huge cost of litigation that goes to that issue, because that is the main issue. [Robert Russell, Borden, Ladner & Gervais, 59:09:35]

The necessary elements in a contested section 45 case must accurately reflect contemporary economic thinking on conspiracies; they should not require excessive labouring on irrelevant economic factors coincidental to the agreement or to the industry under scrutiny. We believe that a conspiracy should be a per se criminal offence and should be guided by the simple and pertinent facts of the case at hand. The Committee, therefore, recommends:

I strongly favour reform of section 45, to narrow its criminal law focus to hard-core cartel behaviour activity, such as price fixing, customer and territorial allocations, and production curtailment. [Tim Kennish, Osler, Hoskin & Harcourt, 59:09:25]

13. That the Government of Canada repeal the term "unduly" from the conspiracy provision (section 45) of the *Competition Act*.

A per se criminal offence without a provision for exceptions would cast a wide net — too wide a net. Horizontal agreements other than that of a cartel would be captured by a strict per se offence. Therefore, a provision for exceptions is necessary. Although recognizing that a long list may have to be drawn to sufficiently reduce the uncertainty surrounding such a specific prohibition, the Committee believes the best approach for an exception would be based, rather than a so-called laundry list of items, on guiding principles. These guiding principles would be premised on known characteristics of a pro-competitive horizontal agreement, such as the existence of economic factors, other than the restraint in question, incorporated into the agreement. Other economic factors would include efficiencies (whether technical or organizational) and innovation. The Committee, therefore, recommends:

[Y]ou need to be careful. The United States, as we all know, has a per se offence, but it is judge-interpreted. It is not statutorily defined. I think you also need to watch that the exemptions don't overwhelm what you're catching. [Lawson Hunter, Stikeman Elliott, 59:09:20]

14. That the Government of Canada amend the *Competition Act* by adding paragraphs to section 45 that would provide for exceptions based on factors such as: (1) the restraint is part of a broader agreement that is likely to generate efficiencies or foster innovation; and (2) the restraint is reasonably necessary to achieve these efficiencies or cultivate innovation. The onus of proof, based on the "beyond a reasonable doubt" standard, for such an exception would be placed on the proponents of the agreement.

[C]reating that sort of bifurcated approach puts an incredible amount of discretion and authority into the hands of the Commissioner. … If you think of a situation where there is a conspiracy that could go one way or the other … the Commissioner would have incredible authority to say, for instance, if you don't do what I like, then I will throw you on the criminal side. [Lawson Hunter, Stikeman Elliott, 59:09:20]

The Committee further recognizes that the two-track approach of pursuing horizontal agreements between competitors provides considerable prosecutorial discretion — although less than provided under the current law. To limit this discretion, the Committee recommends:

15. That the Government of Canada amend the *Competition Act* to add a paragraph to section 45 that would prohibit any proceedings under subsection 45(1) against any person who is subject to an order sought under any of the relevant reviewable sections

of the *Competition Act* covering essentially the same conduct.

[I]t may be that two pharmaceutical companies need to collaborate in the development of the vaccine and need to fix the price for some short period of time to recoup the development costs. That sort of activity would be examined as a strategic alliance and may be exempt. [Robert Russell, Borden, Ladner & Gervais, 59:09:15]

The Civil Track

In its *Interim Report*, the Committee suggested that the government consider modifying the abuse of dominant position provision (section 79) to allow for a civil review of horizontal agreements between competitors. This suggestion may have been premature. Although section 79 deals with joint dominance cases and could in some way be modified to accommodate horizontal agreements that fall under the joint dominance category, we believe that such modifications should not be made. The nature of these horizontal agreements is fundamentally different and incompatible with practices that would be considered potentially abusive behaviour. In other words, a proposed agreement between competitors that may restrict competition only in an ancillary way is an agreement between allies; it is not about an abuser-victim relationship. Consequently, modifications to section 79 to accommodate horizontal agreements that may or may not be anticompetitive may not be the most effective way of pursuing these agreements, and, at the same time, such an approach may risk a loss in effectiveness in pursuing abuse of dominance cases. Indeed, two instruments designed to target two different types of behaviour would be the prudent approach to take.

It strikes me that it will be better if … we can look at these arrangements the same way we look at mergers, with the full panoply of economic analysis ... [Tim Kennish, Osler, Hoskin & Harcourt, 59:09:25]

The Committee is also reluctant to propose that these agreements be afforded a section 92 through 96 merger review. A horizontal agreement may not easily meet the definition given a merger under section 91 and there is no compelling reason dictating that we modify one to accommodate the other when unforeseen consequences may inadvertently arise. Nevertheless, a strategic alliance should be afforded a similar review to that of a merger. The Committee, therefore, recommends:

Our proposal was to focus on the question of whether the agreement was … in … substance price-fixing … or price-fixing element only ancillary to some larger agreement that itself would not be found in violation of section 45. If it were just ancillary to a larger agreement, then the whole agreement would go down the civil track and be reviewed, very much like a merger. [Tom Ross, University of British Columbia, 59:09:30]

16. **That the Government of Canada amend the civilly reviewable section of the *Competition Act* to add a new strategic alliance section for the review of a horizontal agreement between competitors. Such a section should, as much as possible, afford the**

same treatment as the merger review provisions (sections 92 through 96), and should authorize the Commissioner of Competition to apply to the Competition Tribunal with respect to such agreements that have or are likely to have the effect of "preventing or lessening competition substantially" in a market.

[In the] merger provisions of the Act, we have a considerable degree of turmoil now in understanding what the objective … is in terms of recognizing economic efficiency … it's rather premature to try to extend the notion of efficiency to other sections of the Act … until we know … what the view of Parliament is on the role of efficiency in competition law. [Roger Ware, Queen's University, 59:12:15]

The Committee intends that this new section only apply to horizontal agreements between competitors, whether suppliers or buyers, and not to vertical agreements, i.e., agreements between a seller and many buyers or between a buyer and many sellers. The Committee, therefore, recommends:

17. That the Government of Canada ensure that its newly proposed civilly reviewable section dealing with strategic alliances, as found in recommendation 16, apply to agreements between competing buyers and sellers, but not to vertical agreements such as those subject to review under sections 61 and 77 of the *Competition Act*.

In addition to the prospect of a fine or incarceration for committing a criminal offence under the Act, would-be offenders must also consider that (if they are convicted) they may also be ordered to pay monetary damages to any person suffering loss as a result of their criminal conduct. The Committee is aware that moving a practice from criminal treatment and subjecting it to civil review will remove the availability of damages awards under section 36 of the Act. This could have an adverse impact on deterrence and compliance, since it lowers the potential "cost" to the offender of engaging in the conduct. This would not be the case, of course, if the government amends the Act to permit the Tribunal to award damages (as set out in recommendation 8).

[O]utside what would be the new criminal track under a revised two-track approach to conspiracies … you would want to have basically the same efficiency provision … But the nature of that efficiency provision would have to be different from the one we have today in section 96, which never worked for almost 10 years … [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:13:00]

At the same time, however, it does not appear to be the case that damages are commonly awarded as a result of a criminal conviction, and for that reason we do not wish to overstate their value as a deterrent. The Committee believes that, for the same reasons that it is inappropriate to treat certain pricing practices under criminal law, it is equally

inappropriate to permit a remedy of damages to attach to such conduct. If we were to permit damages awards with respect to only a few select practices, but not to other civilly reviewable matters, inconsistency would result in the Act. This underscores the importance of extending the right to claim damages under all civil practices, including those for which transfer into the civil steam is recommended.

When you go down that road and look at that bifurcated model for section 45, … I would alert you to the fact that as the law is currently cast, all activity within the criminal part of the Act can be the basis for a claim for damages. To the extent you remove any part of that activity and put it into the civil part of the Act, it will no longer be subject to a possible claim for damages. It's something you might want to factor into your deliberations. [George Addy, Osler, Hoskin & Harcourt, 59:12:30]

Given the numerous changes we are recommending, the Competition Bureau's Strategic Alliance Bulletin will have to be thoroughly reworked and upgraded to the status of enforcement guidelines. The business community, in the absence of jurisprudence, will need ample guidance from the Commissioner on how the Bureau will treat horizontal agreements between competitors. The Committee, therefore, recommends:

18. That the Competition Bureau establish, publish and disseminate enforcement guidelines on conspiracies, strategic alliances and other horizontal agreements between competitors that are consistent with recommendations 12 through 17 that would amend the *Competition Act*.

Strategic Alliances and a Pre-Clearance Process

As stated above, the Committee accepts the general proposition that no conspiracy law can be written with perfect precision; a number of pro-competitive horizontal agreements will be inadvertently caught by any per se provision, no matter how carefully it is written. The above exception provides some measure of certainty for some contemplated pro-competitive horizontal agreements, yet more is needed to reduce the uncertainty and "chilling effect" that arises in some of the more controversial or borderline agreements. A systematic way of reducing or eliminating a horizontal agreement's prospective liability to criminal sanctions prior to being consummated is required. On this point, there have been two suggestions: a notification process and a pre-clearance process.

Others have suggested approaches based on whether the agreement itself is public. If it were a public agreement, it would get the civil review, whereas secretive agreements would be viewed as per se, illegal, and there are other approaches as well. [Tom Ross, University of British Columbia, 59:09:35]

The notification system would prohibit all secret or covert conspiracies to directly or indirectly fix prices, but would provide an exemption from subsection 45(1) to all

overt horizontal agreements provided that their proponents notify the Bureau before the agreement takes effect. Major deviations from the original agreement would be subject to criminal prosecution. The notification of such an agreement would be optional; there would be no obligation to disclose the facts of any agreement. The Commissioner would also be entitled to request additional information in order to determine whether the agreement should be opposed or altered under a civil proceedings or, as others have coined it, the civil track.

The pre-clearance system would operate much like the advance ruling certificate for mergers pursuant to section 102 of the *Competition Act*. This would be a voluntary reporting system, with a limited cost-recovery fee assessed in return for providing an advance ruling. Under such a system, the Commissioner of Competition would be authorized to issue a clearance certificate if he is satisfied that the agreement, as proposed and implemented, does not substantially lessen competition or poses a threat under section 45 or under the newly proposed civil track. The certificate might or might not grant a time-limited exception from criminal liability and, like the notification system, major deviations from the original agreement would be subject to criminal prosecution.

[T]here have been a number of suggestions that the salvation for some trade-restraining agreements would be the public notification of those agreements that would enable the parties to them to be assured that they wouldn't be challenged. As a policy matter, I think it's undesirable to have agreements that are in contradiction to our general principles simply on the theory — a naive one, I think — that public disclosure of them will deter people from dealing with people who have entered into these kinds of restrictive arrangements. [Tim Kennish, Osler, Hoskin & Harcourt, 59:10:20]

The Committee is of the opinion that both systems have their advantages and disadvantages; however, for a number of reasons, we favour a pre-clearance system. Such a system provides more assurance that contrived or "dressed up" cartel agreements will not slip through the cracks. The Committee, therefore, recommends:

19. That the Government of Canada amend the *Competition Act* to allow for a voluntary pre-clearance system that would screen out competitively benign or pro-competitive horizontal agreements between competitors from criminal liability pursuant to subsection 45(1) of the Act. That the Competition Bureau levy a fee on application for a pre-clearance certificate that would be based on cost-recovery principles similar to that of a merger review. That a reasonable time limit upon application for a certificate be imposed on the Commissioner of Competition, failing

which the applicant is deemed to have been granted a certificate.

In the case where the Commissioner does not grant a pre-clearance certificate, the applicant should be given fair hearing before the Tribunal. The Committee, therefore, recommends:

The experience in other jurisdictions will evidence the fact that lawyers are very clever in the way they write up these arrangements, and describe them using obfuscation and confusing legal documents or burying the filings with the appropriate agency such that people really don't have a good understanding of what in fact is being disclosed. [Tim Kennish, Osler, Hoskin & Harcourt, 59:10:25]

20. That the Government of Canada amend the *Competition Act* to allow individuals who have been refused a pre-clearance certificate for a horizontal agreement between competitors by the Commissioner of Competition be given standing before the Competition Tribunal for a fair hearing on the proposed agreement. That such standing be granted only if the agreement remains proposed and has not been completed.

CHAPTER 5: THE ANTICOMPETITIVE PRICING PROVISIONS

Predatory Pricing

Predatory behaviour occurs when a firm temporarily lowers its prices or expands output or capacity in an attempt to deter new competitors from entering the market or to drive out or discipline competitors who are already there. In all three cases, the predator incurs temporary losses in the expectation of, at the very least, recouping them by raising prices later and from an increased market share. Prior to the 1980s, most economists regarded predation as extremely rare because the barriers to entry in most markets were thought to be low. Consequently, it was believed that the subsequent high prices required to recoup the losses suffered in the predatory period would not be sustainable in the face of new entrants. Moreover, predation would be very expensive; the "prey" would be aware that the period of lower prices would be costly for the predator and might hold on in the hope of eventual profits (in the case of efficient capital markets), or to see the predator attempt to buy it out. Only in the extremely rare event that the predator had greater and better access to external capital would a predatory campaign pay off; although even a takeover or merger would generally be a more successful way of monopolizing the market.

I also would like to commend the Committee for its initiative in taking on reforms … to sections 50, 61, and 75, which have needed attention for a long time. [Donald McFetridge, Carleton University, 59:10:00]

In section 50, where we have the vague wording "at prices unreasonably low", we don't have much jurisprudence … to give an interpretation of it. [Douglas West, University of Alberta, 59:10:40]

Recent economic research, however, challenges this long-held position on the grounds that predation may be a more frequent occurrence than previously thought. Some believe the practice, although still infrequent, is not rare.

Predatory pricing is a criminal offence under paragraph 50(1)(*c*) of the *Competition Act*. Several elements must be established before an offence is proven. The alleged predator must be engaged in a business and have adopted a policy of selling products at prices that are unreasonably low. Both the "policy" requirement and the "unreasonably low" price requirement have raised difficult

[W]ith predatory pricing … [E]very case in Canada has failed because cost isn't properly defined. [Robert Russell, Borden, Ladner & Gervais, 59:10:35]

issues of interpretation. With respect to a policy, one of the following four requirements must be met:

1. It must have the effect or tendency of substantially lessening competition.

2. It must have the effect or tendency of eliminating a competitor.

3. It must be designed to substantially lessen competition.

4. It must be designed to eliminate a competitor.

[T]he Tribunal is dealing with the generic question about avoidable cost: what is avoidable cost, timing issues related to avoidable cost, when the cost became avoidable, and what revenues to consider as part of the test. [Douglas West, University of Alberta, 59:11:40]

The Committee was told that, as simple as the above definition seems, predatory pricing and behaviour are much more complicated to establish in practice. The firm's broad scope in pricing its services (in the case where its marginal cost can approach zero) makes it extremely difficult to distinguish predatory pricing from aggressive price competition. In the case of perishable goods, whose marginal cost is often as close to zero as you can get, selling below cost is a perfectly legitimate business practice.

Indeed, modern thinking even questions whether the hard-to-define marginal cost concept is the appropriate test of predatory pricing. The Committee was told to consider the case of Amazon.com; founded in 1995, the firm has yet to price above cost. Amazon.com is pricing less than its cost, but it is not engaged in predatory pricing. Through low prices, it is investing in a future market share as a new innovator. So there is a temporal aspect to pricing that may not be properly accounted for in the current cost test of predatory pricing.

[W]e create penalties, and the whole point of enforcement is to discourage people from doing bad things. … So a few successful cases on predatory pricing, no matter how long they take, might create the right kinds of incentives to get … the right enforcement stance on predatory pricing. We don't need regulatory powers from the Commissioner to do that. [Roger Ware, Queen's University, 59:12:15]

This example of below-cost pricing which is not predatory pricing was further extended to apply to simple goods such as a razor and razor blades or a number of other complementary products. Apparently, pricing razors below their accounting measures of cost makes good economic sense when it leads to greater sales of razor blades and ultimately greater profit. In this case, what should be compared to today's price is the following: today's average variable cost minus the present value of the firm's expected increased gross margin per unit in the future that is attributable to the low pricing policy. Needless to say, when the investigator has gathered this last bit of information, the

"prey" will have given up the struggle. Clearly, economic theory, as a practical guide to enforcement of predatory pricing, leaves something to be desired.

The VanDuzer Report was sceptical of both the legal framework and its economic underpinnings:

> Designing rules to deal effectively with predation is the thorniest problem related to anticompetitive pricing practices. The effects can be devastating but are extremely difficult to distinguish from the effects of aggressive competition, even with the expenditure of substantial resources. One thing seems clear, the existing criminal provision, suffers from some serious defects as an instrument to provide relief in circumstances where predation exists.[18]

A consensus of competition law experts supports the VanDuzer Report's proposed solution:

> Dealing with predation under section 79 is one solution to these problems. As prescribed by economic analysis … section 79 imposes market power as a threshold for obtaining relief. The abuse provision offers the lower civil burden of proof which may be important given the inherently contestable nature of claims regarding predation.[19]

I [do] not favour the high-penalty deterrence process, because unlike a cartel situation, where it's inherently bad conduct, aggressive price competition is usually good. You're on a sounder path … where you look at moving into a more refined treatment of predation in the context of the abuse-of-dominance provisions in the Act, because it really is a species of that area of monopolization. [Neil Campbell, McMillan Binch, 59:12:15]

The VanDuzer Report suggests other advantages of shifting the prohibition under section 79:

> As well, it requires an assessment of the effect on competition. The Tribunal would be able to consider not only whether there was a prospect of recoupment through supra-competitive pricing, but also the effects of predatory behaviour on the dynamic of competition in the market in which the predation took place. Such effects would include effect of the loss of particular competitors and their prospects for re-entry. The Tribunal could sort out the extent to which it was appropriate to take into account non-efficiency based considerations, such as the fairness of intentionally eliminating a competitor through low prices.
>
> The abuse provision would also permit account to be taken of the particular conditions in the marketplace, including the factors discussed in relation to the new economy ... Where a market was characterized by high levels of

[18] J. Anthony VanDuzer and Gilles Paquet, op.cit., p. 75.

[19] Ibid., p. 75.

> innovation, declining costs and network effects, low pricing which eliminated a competitor might nevertheless be found to be pro-competitive, where the pricing was part of a strategy to introduce a new and better technology and any dominance which resulted was unlikely to be sustained in the face of future innovation.[20]

However, the Commissioner of Competition, the Canadian Bar Association and a number of other stakeholders oppose this suggested change because they believe the criminal status best deters egregious anticompetitive conduct; they favour more enforcement resources, believing the double layer of protection (paragraph 50(1)(*c*) and section 79) against predatory pricing is more appropriate at this time.

[T]his notion of trying to make some changes to the predatory pricing provisions and to bring them over to the civil side … I think it's important to consider the possibility of creating a new section that deals with predatory pricing, but not necessarily under the existing wording of the abuse-of-dominance provision. [Douglas West, University of Alberta, 59:12:40]

The Committee has reservations about this last position, because there is simply insufficient case law to validate the deterrent effect of paragraph 50(1)(*c*). The Committee cannot just ignore the predatory pricing provision's inactive and ineffectual history, which includes only two contested cases (both of which are more than two decades old). Moreover, the Committee is unsure about a court being the right venue for the intricate economic analysis needed to discern between predatory and aggressive, pro-competitive pricing; the Competition Tribunal appears better able to judge this behaviour. In any event, a consensus has formed on the use of the abuse of dominant position provision as a vehicle for bringing a predatory pricing case before the legal authorities — a provision that requires that the alleged predator has "market power" and that the practice in question would "prevent or lessen competition substantially." For these reasons, the Committee recommends:

21. That the Government of Canada repeal paragraphs 50(1)(*b*) and 50(1)(*c*) of the *Competition Act* and amend the Act to include predatory pricing as an anticompetitive act within the abuse of dominant position provision (section 79).

20 Ibid., p. 75.

Price Maintenance

Price maintenance is the practice whereby a firm attempts to either set or influence upward the minimum price at which another firm further down the manufacturer-wholesaler-retailer distribution chain can sell its product. Although resale price maintenance is not a pervasive practice throughout the business sector, it is one of the most common pricing restraints found in the marketplace. It may take place either vertically, for example between a wholesale supplier and a retailer that resells the supplier's products, or horizontally, for example between competitors who agree to impose resale price maintenance on those who resell their products.

In terms of vertical price maintenance, typically the example given would be ... Say, for example in the electronics industry, … You can sit down, you can go into a sound room, and you can listen to a whole bunch of different types of speakers. You can listen to a bunch of different types of CD players. You can get a real feel for the quality differences. But it costs … a lot of money to put that sound room in place. If somebody else could come along and free ride off that by locating down the street or a few blocks away, selling exactly the same products but at a substantially reduced price, … [the service providing store] wouldn't be able to continue to provide the consumer with the benefit of that. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 65:12:30]

Since 1951, following the recommendations of the MacQuarrie Commission, price maintenance has been a criminal offence under section 61 of the Act. Thus, it is illegal for any person engaged in a business to try to "influence upward or discourage the reduction" of the price at which someone else engaged in a business sells the product by "any agreement, threat, promise or like means." In 1960, the law was amended to add the current defences to the related offence of refusing to supply a customer because of the customer's low pricing policy. These defences are listed in subsection 61(10) as:

- using products supplied as loss leaders (the "*Loss Leader Defence"*);
- using products supplied not for the purpose of selling them for a profit but to attract customers to buy a rival's products (the "*Bait and Switch Defence*");
- engaging in misleading advertising in respect of the products supplied; and
- not providing the level of service that purchasers of the products might reasonably expect (the "*Service Defence*").

So the pro-competitive aspect of it, of resale price maintenance is it provide dealers with a margin to invest in providing services, to expand the demand for the product. … when you expand the demand for the product, you increase aggregate wealth in the economy. So it's pro-competitive in that sense. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 65:12:30]

On the other hand, requests, discussions, moral suasion, or suggestions to this end are considered to be much the same as setting a suggested list price and are permissible (subsection 61(3)). Similarly, under subsection 61(4), if the suggested price appears in an advertisement, it must be expressed in such a way that it is clear to any

person who looks at the advertisement that the product may be sold at a lower price; otherwise the supplier will be found to have attempted to influence the price upward.

In any vertical relationship, let's say between a manufacturer and a distributor, suppose the manufacturer owned the distributor? Then they could decide whatever terms and conditions they wanted that product to be sold under, including price, the quality of the sales personnel, their qualifications. The manufacturer could determine everything down to the lighting in the store. And we wouldn't consider that to be anti-competitive. So why would we consider it to be anti-competitive if Sony tried to do some of those things at arm's length? [Roger Ware, Queen's University, 65:12:30]

The Committee is more easily convinced of the economic rationale for prohibiting horizontal price maintenance. Where suppliers agree among themselves to set the resale price of their products, price competition among downstream competitors is precluded. Where the resale price is the more visible of the two, the maintenance of that price may facilitate collusion among suppliers. By subtracting the retailer and wholesaler profit margins from the minimum fixed retail price, manufacturers in effect fix their own prices of the product. The Committee was also made aware that resale price maintenance could facilitate the work of a retailer cartel. History suggests that this had long been the case of pharmaceutical retailers whereby drug stores pressured manufacturers of the products they carried to impose resale price maintenance.

You take price maintenance. We have a very strict law here. There's no necessity for an agreement to be in place … The necessity for agreement in U.S. law allows the so called Colgate doctrine, which means: they can unilaterally sell, you won't sell my product for less than, you just can't have an agreement. … So price maintenance that would be unlawful in Canada occurs in the U.S. all the time. That's a cross-border legal issue that I have to deal with monthly … [because] the law is different here. [Robert Russell, Borden, Ladner & Gervais, 65:11:15]

Vertical price maintenance is less obviously an anticompetitive act. The classical example of such price maintenance is where a supplier requires someone to whom it sells, perhaps a retailer but also a wholesaler, to maintain prices at a particular level as a way of encouraging that retailer or wholesaler to engage in competition on something other than price. A higher retail margin thus encouraged the retailer to engage in providing a high level of service to clients or to ensure that the brand image associated with the product is maintained and not sullied in any way.

[P]rice maintenance provision which deals with these vertical pricing arrangements you're talking about is a very effective section for us. [R.W. McCrone, Competition Bureau, 64:09:40]

From the consumer's perspective, vertical price maintenance results in more services, which we would regard as good, but higher prices, which we would view as bad. The Committee was told that, on balance, the decision of how to market a product and how to design a distribution system should be left up to the manufacturer. Prohibiting resale price maintenance under the per se rule is effectively regulating the manufacturer's decisions on how best to maximize the sale of his products. By way of an analogy, we do not prohibit by law high levels of advertising even when such advertising raises prices; for the same reason we should not prohibit vertical price maintenance under a per se rule. So to the extent that there are efficiency justifications

for price maintenance, the per se criminal prohibition in the Act is over-inclusive.

I just don't agree that criminal prohibition is warranted, especially where there is no requirement for demonstrating adverse effects on competition. They have to be presumed and … there are many potential circumstances in which there are pro-competitive benefits that come from it. In the vertical situation we're not talking about controlling the price of a product amongst all the competitors, we're talking about controlling perhaps the pricing and positioning of the product from one supplier which is going to be disciplined by other parties in the marketplace if in fact they're not dominant. [Tim Kennish, Osler, Hoskin & Harcourt, 65:12:35]

All witnesses, except Bureau officials, who commented on price maintenance had a recurring theme: vertical price maintenance should be decriminalized and horizontal price maintenance should be moved to the conspiracy provision. The Bureau, the lone dissenter, could only offer a higher success rate when prosecuting under a per se offence as its reason for departing from expert opinion. The Committee, however, must remind everyone that competition policy is not about winning and losing cases; it is about designing a framework whereby an efficient business sector can deliver products and services at competitive prices. Moreover, the Committee sees no social benefit in risking convictions of, and a "chilling effect" on, pro-competitive vertical price maintenance under the criminal section of the Act, when the civil section offers a more reasonable approach and a better result. In decriminalizing vertical price maintenance, competition experts suggested that shifting this act under the abuse of dominant position provision (section 79) would be the preferred route. In this way, the treatment of vertical price maintenance under the law will better conform to contemporary economic thinking.

[I]n the area of pricing practices … [y]ou've had the benefit of Professor VanDuzer's detailed report, which has examined the fact that some of those laws are economically no longer really very modern. [Neil Campbell, McMillan Binch, 59:11:25]

The Committee understands that a section 79 review has two advantages: the practice would receive a full hearing on its likely economic effects and would also be subject to a lower burden of proof (from "beyond a reasonable doubt" to "on the balance of probabilities"). Another difference, which could be an advantage or a disadvantage depending on one's perspective, is that section 79 will require an assessment of the market power of the individual firm engaging in price maintenance. According to the VanDuzer Report, the market power test is an advantage because economic factors can easily be identified for discerning anticompetitive from pro-competitive cases. Indeed, the VanDuzer Report suggests three economic indicators of anticompetitive vertical price maintenance:

I would encourage you … to look at the decriminalization of the pricing practices … those laws are out of date and out of sync with good economics. [Neil Campbell, McMillan Binch, 59:12:40]

1. The person implementing price maintenance (the "Supplier") has market power, which suggests that customers may have limited opportunities to switch suppliers.

2. The Supplier does not have an efficiency-based justification, such as the desire to increase service or prevent brand-impairing practices, which would include "loss leadering" or misleading advertising.

3. The Supplier was induced to implement price maintenance in relation to one customer by another customer who competes with the first.[21]

[There] is the need to reform the arcane criminal provisions in the Act — not just section 45, but many of the provisions relating to the pricing practices, including predatory pricing, price discrimination, and price maintenance. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:11:15]

At the same time, the VanDuzer Report is unsure if the section 79 market power test is appropriate for vertical price maintenance cases.

The Committee accepts all of the above reasoning. We believe that where the law can be modernized to better reflect conventional economic thinking, which in this case is able to properly distinguish between anticompetitive and pro-competitive incidences of vertical price maintenance, we should change the law. Given the recommended changes of section 79 (Chapter 6), reducing the bluntness of the Act in terms of vertical price maintenance should lessen the "chilling effect" on pro-competitive instances. The Committee, therefore, recommends:

22. That the Government of Canada repeal the price maintenance provision (section 61) of the *Competition Act*. In order to distinguish between those practices that are anticompetitive and those that are competitively benign or pro-competitive, that the Government of Canada amend the *Competition Act* so that: (1) price maintenance practices among competitors (i.e., horizontal price maintenance), whether manufacturers or distributors, be added to the conspiracy provision (section 45); and (2) price maintenance agreements between a manufacturer and its distributors (i.e., vertical price maintenance) be reviewed under the abuse of dominant position provision (section 79).

When it comes to horizontal price maintenance, that ought to be dealt with under a new section 45. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:12:25]

21 Ibid., p. 44.

Price Discrimination

Price discrimination is a marketing practice whereby a supplier of goods or services charges different prices to different customers (whether other businesses or final consumers) and these price differentials do not accurately reflect differences in costs of serving the different customers. To be found discriminating on the basis of price, a firm has to meet the following conditions: (1) the firm must have market power to set prices (otherwise, consumers can choose to purchase from a competing supplier); (2) the firm must be able to identify classes of consumers with different price sensitivities; and (3) consumers have only a limited opportunity to resell to each other (otherwise, consumers would arbitrage these prices to the lower price offered).

If I were to come to you and say "I'll … come and pick the product up at your door, or I'll warehouse the product, or I'll perform some other function for you and save you money, if you give me a deal," it's arguable … whether you could give me a discount in recognition of that pro-competitive initiative. It may be that I'm just a better negotiator. That maybe I'm going to do something for you in a different market. Buy more goods on a different market from you if you give me a better discount. What [the criminal offence] does is it just chills the negotiation process ... It would be a criminal offence for you to give me a better discount. So the whole competitive process that one would normally see between supplier and customer is chilled. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 65:12:30]

Price discrimination is a criminal act that extends only to "sales" of "articles" under paragraph 50(1)(*a*) of the Act and to promotional allowances under section 51. These provisions were introduced in 1935 in response to concerns of unfairness to small business, particularly in the grocery subsector, with the emergence of large retail discount and chain stores and following the *Report of the Royal Commission on Price Spreads*. Because paragraph 50(1)(*a*) only applies to "sales" of "articles," leases and services are not covered. If the purchasers do not carry on business in the same market, such as the case where one is a final consumer and the other is a business, there is no offence. Volume or quantity discounts are exempted. There must be knowledge of each element of the offence. The supplier must have knowledge that the sale is discriminatory. Section 51 makes discrimination other than on the basis of price (i.e., differential access to promotional allowances) a criminal offence in some circumstances.

On price discrimination, we're really weak in Canada compared to the U.S. because in the U.S. you can discriminate in price on the basis of volume. So you can, as a store for example, buy a product for less if you buy 100 than if you buy two. It's completely arbitrary in our law. You can make a differentiation between one and two, or one and 5,000 — whatever you want — and set your price on that level. That's the law in Canada. You don't have to justify it on the basis of cost as a manufacturer. In the U.S. what you have to do is you can't discriminate unless you can justify it. [Robert Russell, Borden, Ladner & Gervais, 65:11:15]

Although price discrimination by definition means treating individuals or groups of consumers differently and may create an "unlevel playing field" when the product is an input into another product, it is not an inherently anticompetitive practice. It is often pro-competitive to charge different prices to different consumers when there are different costs attached to serving them (in the same way as volume and quantity discounts imply different costs and are not anticompetitive in and of themselves). Price

discrimination may also result in additional sales, for example, to children and seniors who would not otherwise purchase the product. To the extent that the consumption of the good or service increases as a result, economic efficiency is being promoted.

Price discrimination is commonplace. For instance, a bank that offers students no-fee banking services in order to gain their loyalty later on in their lives is practising price discrimination. Many non-price techniques with similar aims to price discrimination could also be implemented to discriminate between consumers. Two classic examples are tied sales and multi-part pricing policies. The VanDuzer Report explains the tied selling technique:

There are questions as to whether the sections on predation and price discrimination, for example, should be decriminalized. People have been trying to address this for many years, and there are questions about the proper ambit of the abuse-of-dominance provision, among others. [Calvin Goldman, Davies, Ward & Beck, 59:10:50]

> At one time, IBM had a monopoly on certain types of tabulating equipment. Different customers valued IBM's equipment quite differently based on the amount that they used the equipment. However, instead of using price discrimination to get the maximum price that each customer was willing to pay, IBM forced customers to buy tabulating cards from the company, and by charging a price for tabulating cards in excess of their cost, IBM was able to discriminate among its customers according to the intensity of their use of the equipment. Block booking and commodity bundling are other examples of non-price requirements imposed by sellers that succeed in enforcing effective price discrimination.[22]

Examples of multi-part pricing techniques of executing price discrimination are: (1) cab fares that include a lump-sum fee upon engagement and charges per unit of distance and/or time; (2) newspaper, magazine, radio and television pricing with two revenue streams — one from advertisers and one from subscribers; (3) fairground entry fees and ride tolls; (4) cover charges at bars and night clubs that are in addition to prices for drinks; (5) automobile licence fees and automotive gasoline taxes; and (6) slotting fees or slotting allowances charged by retailers on top of the retail price mark-up.[23]

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22 Ibid., p. 6.

23 Most multi-part pricing policies are two-part, as they include only two sources of revenue.

The VanDuzer Report concludes that:

> There is no question that the current criminal price discrimination provision is not adequate to address anticompetitive price discrimination. The economic analysis … concludes that price discrimination is not anticompetitive in many circumstances. Whether there is any possibility that price discrimination will have an anticompetitive effect will depend on the facts of each case. The current provision does not require the discriminating supplier to have market power, a prerequisite to true discrimination, nor does it require any assessment of the effect of discrimination on competition. To this extent the provision is over-inclusive. At the same time, by failing to include discrimination in services and discrimination in forms of transactions other than sales, the provision excludes important areas of economic activity in the contemporary marketplace. In its present form, the criminal price discrimination provision is not an accurate tool for addressing anticompetitive behaviour and imposes excessive compliance and monitoring costs on business. Because price discrimination is a criminal offence, this chilling effect is exacerbated.[24]

[T]he best and most effective way to deal with predatory pricing, as well as geographic price discrimination and vertical price maintenance, is to repeal the current provisions and deal with this conduct under reinforced abuse-of-dominance provisions. By "reinforced" I mean you need to create an administrative penalty of the type you currently have in the deceptive marketing practices provisions of the Act. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:12:25]

The VanDuzer Report makes a very compelling case for decriminalizing price discrimination cases, and a consensus among competition experts has followed. The Committee, therefore, recommends:

23. That the Government of Canada repeal the price discrimination provisions (paragraph 50(1)(*a*) and section 51) of the *Competition Act* and include these prohibitions under the abuse of dominant position provision (section 79). This prohibition should govern all types of products, including articles and services, and all types of transactions, not just sales.

[24] J. Anthony VanDuzer and Gilles Paquet, op.cit., p. 72.

CHAPTER 6: ABUSE OF DOMINANCE

Substantive Elements

Sections 78 and 79 together form the so-called "abuse of dominance" provisions, constituting a key element of Part VIII of the *Competition Act* dealing with "reviewable practices." These sections were enacted in 1986 and replaced the previous criminal offence of being party to, or to the formation of, a monopoly.

Section 79 permits the Commissioner to apply for, and the Tribunal to make, an order prohibiting a person or persons from engaging in anticompetitive acts. Section 78 provides a list of some of these so-called "anticompetitive" acts for the purposes of invoking section 79; the list in section 78 is not exhaustive and so does not narrow the application of section 79 to only the practices specifically listed in section 78. In fact, the Tribunal has ventured outside this list on a number of occasions.

I think the Tribunal, when it has articulated the need for a market power test in the abuse-of-dominance provisions, has never gone further and told us what degree of market power you need. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:13:00]

Some of the anticompetitive acts contemplated in Part VIII may also be addressed, in the alternative, in criminal proceedings under section 45 or 61, or paragraph 50(1)(*c*) of the Act. The Act requires that either one approach or the other be adopted, but not both.

To get an order under section 79, the Commissioner must convince the Tribunal, on the "balance of probabilities" (the standard of proof in civil law), of three elements:

1. That one or more persons *substantially or completely controls,* throughout Canada or any area of Canada, a class or species of business.
2. That the person or persons have engaged in or are engaging in a *practice* of uncompetitive acts.
3. That the practice has had, is having, or is likely to have, the effect of *preventing* or *lessening competition substantially* in a market.

Where these three elements are present, the Tribunal may make a cease and desist order. In addition to ordering the cessation of the anticompetitive activity, the Tribunal may also, to the extent that it is reasonable and necessary to overcome the effects of the activity, make an order requiring any person to take certain action, including the divestiture of assets or shares. The order must be only for the purpose of restoring competition in the relevant market and may not be for the purpose of imposing punitive measures.

The phrase "substantial or complete control" in the first element is the same wording used in the criminal monopoly section that preceded the current abuse of dominance rules.[25] But what degree of control is "substantial"? The case law interpreting the predecessor criminal provision suggests that control must approach 100% of the relevant geographic and product market, but subsequent cases have refined this analysis considerably.

Predatory pricing can be captured under section 79.… And also we had a panel of experts who suggested that price discrimination could already be dealt with under section 79 of the civil provisions also. [R.W. McCrone, Competition Bureau, 64:09:40]

The Tribunal must, as the first step to determining whether abuse of dominance exists, define the "relevant market." Market definition has two aspects: the product market and the geographic market. Determining the relevant market for a product is a complicated undertaking, involving consideration of such factors as direct and indirect evidence of substitutability and functional interchangeability of products, trade views on what constitutes the same product, and the costs of switching from one product to another.

In addition to defining the relevant product market, the Tribunal must also define the relevant geographic market. It does so by reference to the boundaries within which competitors must be located if they are to compete with each other and where prices either tend toward uniformity or change in response to each other. The Tribunal has recognized that the relevant market (so defined) will have a significant impact on any conclusion regarding the effect of the dominant firm's behaviour on competition. In general, however, the more broadly the market is defined, the less likely it is that the firm will possess market power and that its behaviour will be found to substantially lessen competition.

25 In section 2 of the *Combines Investigation Act*.

Once the market is defined, the Tribunal will address whether there exists "substantial or complete control" over that market. The Tribunal has equated this rather ambiguous phrase to mean market power. "Market power" may be understood to be the case of a dominant player that has the ability to raise its prices (or reduce product quality) in a non-transitory way (the longer term, usually defined as two years) without suffering a loss in profit.

With respect to market power, high market share alone will not give rise to a presumption of dominance. In *Laidlaw*,[26] the Tribunal held that dominance would not be presumed where market share is below 50%. The Tribunal has yet to deal with a contested claim of dominance where the allegedly dominant firm has a market share of less than 85%. Interestingly, the 50% threshold enunciated in *Laidlaw* is higher than the 35% threshold set in the Bureau's *Merger Enforcement Guidelines* and the *Predatory Pricing Enforcement Guidelines*. More jurisprudence on this issue would be helpful.

[I]n terms of pricing provisions … The current provisions under the abuse of dominance might cover that kind of conduct, but it's a bit of a grey area because the firm that's entering the new market may not in fact be dominant in that market. The abuse-of-dominance provisions refer to a firm having substantial or complete control of a class or species of business. Now, you could try to sandwich the conduct under the abuse-of-dominance provision. It's not clear that this is what it was intended for …
[Douglas West, University of Alberta, 59:12:40]

Barriers to the entry of new competition also constitute an important factor. In determining the existence of a barrier to entry, the Tribunal will examine factors such as sunk costs[27] and economies of scale, as well as technical and regulatory barriers. Sunk costs or economies of scale on their own are unlikely to be regarded as sufficient. The Tribunal must also consider the number of competitors, their relative market shares, and whether there is excess capacity in the market. Notwithstanding the guidance provided by the Tribunal in past cases, predicting when the Tribunal will find dominance will often be difficult.

The second element to be considered in section 79 is whether the practice has the effect of lessening competition substantially (this is more commonly referred to as an "SLC" test). Determining whether a practice will result, or has resulted, in an SLC is a difficult determination. What meaning is to be given to the term "substantial"? In *Nutrasweet*, approximately 90% of the market was controlled by the leading aspartame company. Although a

26 Director of Investigation and Research v. Laidlaw Waste Systems Ltd. (1992), 20 C.P.R. (3d) 289.

27 The costs that the new entrant will not recoup if he subsequently exits the market. Advertising is the most common example of a sunk cost.

high market share may suggest dominance, such a high level may not be necessary to prove dominance. The Committee anticipates that the meaning of the term will in time become clear through jurisprudence.

[Y]ou have the right … idea … with respect to modernizing and decriminalizing … the pricing provisions in the Act and moving them into … the abuse-of-dominance regime. This will provide a … coherent and single place in which you can think about those types of behaviour … where there is a competition concern as opposed to the many situations where there is not. [Neil Campbell, McMillan Binch, 59:11:25]

The final element that must be demonstrated under section 79 is a "practice of anticompetitive acts." Although "practice" was not defined in *Nutrasweet*, the Tribunal appears to have set the bar quite low, stating that a practice may exist "where there is more than an isolated act or acts." Moreover, a number of different isolated anticompetitive acts might constitute a practice when taken together.

Anticompetitive Pricing Practices: The Civil Approach

As discussed in the previous chapter, the Committee believes that the current approach of treating the practices in sections 50, 51 and 61 as criminal offences is inappropriate in the modern business environment. These provisions — owing to their possible efficiency-enhancing or pro-competitive effects — would be more effectively addressed as reviewable trade practices under Part VIII of the Act, and more specifically under the abuse of dominance rules. At the same time, as the VanDuzer Report and other commentators have suggested, there are certain conceptual difficulties in treating the pricing practices under section 79.

The first objection is that removing these practices from criminal treatment to civil review may undermine the deterrence value of treating them as criminal offences. However, the Committee believes that this same deterrence could be accomplished by empowering the Tribunal to levy monetary penalties under section 79. Furthermore, the criminal law treatment could remain in place for practices, such as hard-core cartel activity, that are without redeeming social value.

A remedy based on damages and fines seems to be a sensible deterrent. You can move that into the civil side without having the problems on the criminal side. [Jeffrey Church, University of Calgary, 59:10:55]

The second objection is not as simply understood. It requires the enunciation of a single legal test to unify under the abuse of dominant position provisions the different legal tests which the Crown, or the Commissioner as the case may be, must meet to succeed before the Court or Tribunal. In addition to the different legal tests existing under the criminal pricing sections and section 79, the different

standard of proof in the criminal provisions (i.e., "beyond a reasonable doubt") must be addressed.

To obtain a conviction under paragraphs 50(1)(*b*) or 50(1)(*c*), the Crown is merely required to show that the policy has, or is designed to have, the effect of lessening competition *or* eliminating a competitor. Paragraph 50(1)(*a*) and sections 51 and 61 require only that the practice itself be proven (the per se approach) in order to secure a conviction, that is there is no need to show that a lessening of competition has occurred. In both cases, the Crown must prove the offence according to the criminal standard of proof, that is, "beyond a reasonable doubt." By removing or shifting those provisions from criminal prosecution to section 79, the Tribunal would consider the competitive effects or the efficiencies resulting from the practice, and would make its determination accordingly. The result, in the Committee's view, would be a better approach for dealing with these practices, one that is more consistent with sound economic analysis. However, if we are going to treat these practices as civil matters, it is necessary to enunciate the single test that will apply to any application brought under section 79.

[I]f you put a civil administrative penalty power into the abuse-of-dominance provisions, you would retain that deterrence effect of the law. And if you further amended the abuse-of-dominance provisions to eliminate the words "substantially or completely control", then the anti-competitive test would simply be substantial lessening of competition, which is the same test that you have right now in the predatory pricing provisions. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:12:25]

The obstacles to creating a single test under section 79 to permit both criminal and civil practices to be addressed may, in fact, not be as significant in practice as the legislation suggests. With respect to paragraph 50(1)(*a*) and sections 51 and 61, the Committee has already stated that those practices should be subject to an SLC test. Moving them to section 79 would have this effect. For its part, the Bureau does not appear to have pursued conduct that does not prevent or lessen competition substantially; this suggests that such an amendment would be in line with current enforcement practice.

The thing that comes with criminal sanctions is the possibility of prison terms in some cases, so you wouldn't replace that on the civil side. Also, just the stigma of a criminal record has a deterrent effect that you wouldn't get on the civil side. I don't think, really, that fines on the criminal side and administrative penalties on the civil side are really comparable. One is clearly designed to penalize for criminal behaviour, and the other I think is more designed to encourage compliance with orders of the Tribunal. [R.W. McCrone, Competition Bureau, 64:10:30]

Furthermore, the Bureau's *Enforcement Guidelines on the Abuse of Dominance Provisions* seem (the "Abuse Guidelines") to suggest that the Bureau does not consider there to be any significant difference between the thresholds. This inference is drawn from the same 35% single-firm "safe harbour" found in the criminal *Predatory Pricing Enforcement Guidelines* and the civil *Merger Enforcement Guidelines*. So this suggests that the

amendment would only clarify the law and enhance its enforceability, without altering it in substance.

So the abuse-of-dominance provisions basically would have a similar anti-competitive threshold and similar deterrence power in the form of an administrative fine that the criminal provision today has, except you wouldn't have to deal with the criminal burden of proof. That's … the most effective way of dealing with not only predatory pricing but also price discrimination and the other pricing practices. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:12:25]

With respect to the "eliminating a competitor" test in paragraphs 50(1)(*b*) and 50(1)(*c*), the Committee believes that this offends the overriding spirit of the *Competition Act*, which is to preserve the process of competition and not competitors specifically. Moreover, the Bureau's *Predatory Pricing Enforcement Guideline*s and the Abuse Guidelines, make it quite clear that the focus of the Bureau's analysis is upon the likely impact of conduct on competition, not on individual competitors. Moving these practices to section 79 would make them subject to the SLC test and to the civil standard of proof. This would remove the chilling effect that currently results from treating these practices as criminal offences. Instead, the practices would be subject to a more appropriate treatment, i.e., one that takes into consideration possible efficiency gains.

For all these reasons, the Committee recommends:

24. That the Government of Canada amend the *Competition Act* by deleting paragraph 79(1)(*a*).

In fact, the Supreme Court of Canada told us we need a greater degree of market power because of the presence of those words "substantially or completely controlled." So if we get rid of those words, we simply have the general market power requirement we have with respect to all of the other provisions of the Act that have this substantial lessening of competition test, which is a lower anti-competitive threshold, and the same one that you currently have in the predatory pricing provision. So you wouldn't be losing anything by shifting over to the abuse-of-dominance provisions. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 59:13:00]

This amendment would bring the wording of section 79 into closer conformity with the concept of market power as it has evolved through judicial interpretation.

Finally, a word on guidelines. The Committee recognizes that the Bureau's current Abuse Guidelines may need to be revised and expanded in order to accommodate the expanded scope of section 79. Many issues may need to be addressed including, for example, a minimum market share for assessing market control, the best analytical framework for assessing when price discrimination and vertical price maintenance are anticompetitive acts, as well as appropriate approaches to dealing with so-called price predation in the civil context. The Committee, therefore, recommends:

25. That the Competition Bureau revise its *Enforcement Guidelines on the Abuse of Dominance Provisions* in order to be consistent with the addition of the anticompetitive pricing practices (paragraphs 50(1)(*a*) and 50(1)(*c*) and section 61) to section 79 of the *Competition Act*.

I think we have a very good abuse-of-dominance framework that applies to most industries ... The abuse guidelines that have just been issued are very well done. They're exceptional. The Bureau is to be commended for that perspective. [Jeffrey Church, University of Calgary, 59:10:15]

CHAPTER 7: MERGER REVIEW

Merger Review Process

The *Competition Act* provides for the civil review of mergers (sections 91 through 96) by the Competition Tribunal. On application by the Commissioner of Competition, the Tribunal may issue a prohibition or divestiture order with respect to a merger that is deemed to prevent or lessen competition substantially. However, before such orders are granted, varied or denied by the Tribunal, a well-established review process must take place. As a starting point, the Committee will provide a simple sketch of this merger review process, which will provide the necessary background to comment on the operations and enforcement of the merger provisions in the Act.

On the other issue, from an enforcement perspective, there's a lot of discussion in the business about how few cases there are and how much guidance is available to the public at large and the business and consumer legal communities about how decisions are made. This issue has been debated probably longer than private access, but I think it's time we institute some form of formal decision publication process. [George Addy, Osler, Hoskin & Harcourt, 59:11:15]

Section 91 of the *Competition Act* sets forth the definition of a "merger," which is deemed to occur when direct or indirect control over, or significant interest in, the whole or a part of a business of another person is acquired or established. The principal issue in this section is the interpretation of the words "significant interest," which is considered to occur when a person acquires or establishes the ability to materially influence the economic behaviour of the business of a second person (i.e., block Director resolutions or make executive decisions relating to pricing, purchasing, distribution, marketing or investment). In general, a direct or indirect holding of less than a 10% voting interest in another entity will not be considered a significant interest. However, a significant interest may be acquired or established pursuant to shareholder agreements, management contracts and other contractual arrangements involving incorporated or non-incorporated entities.

The EU has a process where, even though a transaction isn't challenged, a decision is released describing how the agency went through its review, what its findings were, and what it considered important or not important. I think that would serve as a very useful public information service for the Bureau to adopt. [George Addy, Osler, Hoskin & Harcourt, 59:11:15]

In general, a merger will be found to be likely to prevent or lessen competition substantially when the parties to the merger would more likely be in a position to exercise a materially greater degree of market power in a substantial part of a market for two years or more. Market power can be exercised unilaterally or interdependently with other

competitors and its ascertainment will be determined according to the following Bureau screening processes:

1. The Bureau will define the relevant markets, each of which consists of determining substitute products and services of rivals of the merging parties, both from a product and a geographic dimension. This will include all products and services that customers would likely turn to in response to a small but significant, non-transitory increase in prices or a reduction in quality and variety of the products or services offered by the merging parties (the "hypothetical monopolist" test of a 5% price increase for up to two years). The geographic dimension of the market would be determined similarly; therefore, it is likely that different products will have different geographic dimensions.

The Bureau does publish, in each merger case, aspects of its decision. What people are saying is there's not enough core analysis necessarily there for us to judge the next case. The contest, however, is how much can you disclose of the confidential information that gives rise to the analysis? [Robert Russell, Borden, Ladner & Gervais, 59:12:05]

2. The Bureau will then calculate and analyze market share and concentration thresholds to distinguish markets that are unlikely to be anticompetitive. The markets that do not surpass the requisite thresholds (so-called "safe harbours") will be screened out. The unilateral exercise of market power threshold is 35% of the post-merger pro-forma market share of the merging parties (sales volume or production capacity). The interdependent exercise of market power threshold incorporates a 65% market share held by the four largest firms in a post-merger market and a 10% market share held by either of the merging parties.[28]

[W]hen you're sitting in the room negotiating the resolution, you also talk about what should be published, and it can interfere with some of the remedy. If you're having to divest of a core asset, if you put too much out there, it becomes a fire sale, which makes it more difficult to resolve. If you're going to give me a penny for my asset or $100 million for my asset, you're going to have a different negotiation coming up with a resolution. [Robert Russell, Borden, Ladner & Gervais, 59:12:10]

3. Given that the Act requires that the Tribunal shall not find that a proposed merger prevents or lessens competition substantially solely on the basis of evidence of concentration or market share, a complete competitive effects analysis will then be performed on those markets where the shares of the merging parties' sales or production surpassed the "safe harbour" thresholds. The Bureau will evaluate many relevant factors, as listed in section 93, such as: foreign competition, availability of acceptable substitutes, barriers to entry, absolute cost advantages, sunk or irrecoverable costs, the time it would take a potential competitor to become an effective competitor, effective

[28] There is no economic rationale for these thresholds over that of others. Simply put, an effective merger review process demands market share anchors, but why these thresholds were chosen over others has never been made clear.

remaining competition, the removal of a vigorous and effective competitor, change and innovation, business failure and exit, and other criteria.

4. The Act recognizes that changes in regulations, developments in new technologies, and the sweeping forces of globalization will have implications on the structure of industry. If the elements of the efficiency exception (section 96) are met (these are cost savings to the economy and are not merely purchasing power savings due to any enhanced ability to squeeze better prices out of a supplier, and that these efficiencies could not be attained if the merger did not proceed), where they would "offset" or are "greater than" the anticompetitive concerns, the Bureau would not pursue the merger any further. The onus of proof of this exception before the Tribunal is put on the merging parties.

[U]nder a total surplus approach, the Competition Tribunal would be prohibited from issuing an order in respect of an anti-competitive merger if it found that the overall effect of the merger on the economy likely would be positive. In other words, if the gain to producers resulting from the cost savings and other efficiency gains likely to be brought about by the merger were greater than the loss to society attributed to the anti-competitive effects, the Tribunal would not … issue an order in respect of the merger. In this very complicated analysis, wealth transfers from consumers to producers are treated as neutral, because they have no bearing on the aggregate level of wealth in the economy. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 65:11:55]

Merger Review Workload and Service Standards

Virtually every witness appearing before the Committee admitted that the Bureau has faced an unprecedented number of merger reviews over the past several years, which has, and continues to put, extraordinary pressure on its Mergers Branch staff. Table 7.1 provides the data to back up the first part of this claim. Excluding asset securitizations (which, since 1999, have been exempted from filing), merger filings have hovered about 340 per annum in the past four years, which is up more than 70% from the average of about 200 filings per year recorded in the first half of the 1990s. So the trend is definitely up over the past decade, but it is also up over the past five years, with 373 mergers being filed in 2000-2001, the highest ever.

I have submitted for consideration a one-month initial review followed by a four-month timeframe. If, after the first month, the Bureau does not go into a full-scale investigative mode, the merger is cleared. If they do go into that mode, then there is a fixed period … of four months … to complete the Bureau's investigation. [Calvin Goldman, Davies, Ward & Beck, 59:09:20]

Table 7.1
Number of Transactions (%) — 1995-2001

Business Line	1995-1996	1996-1997	1997-1998	1998-1999	1999-2000	2000-2001
Pre-merger Notification Filing	57	58	84	109	92	73
Advance Ruling Certificate Request	117	181	219	174	209	255
Other Examinations	17	23	17	26	60	45
Sub-total	**191**	**262**	**320**	**309**	**361**	**373**
Securitization	36	52	72	52	64	0
Total	**227**	**314**	**392**	**361**	**425**	**373**

Source: Competition Bureau Merger Branch, *Merger Review Performance Report June 2001*, 2001.

I recommended earlier that in the area of merger review consideration be given to trying to define the time periods with statutory certainty so that business persons engaged in transactions, third parties interested in transactions and making submissions to the Bureau, … know there are fixed time periods, as opposed to the current service standard guidelines …This would promote certainty. [Calvin Goldman, Davies, Ward & Beck, 59:09:15]

Data submitted to the Committee provides evidence of the second part of the claim. The Mergers Branch at the Bureau averaged 38 full-time equivalent person-years in the early 1990s, but has gradually increased to 57 in 2000-2001. Therefore, the Bureau's Mergers Branch has grown by just less than 50% over the employment levels of the early 1990s, which is significantly below the merger filings growth rate of more than 85% in the same period.[29] Moreover, Table 7.2 indicates that the complexity of mergers that the Bureau has had to review is also increasing. Complex mergers and very complex mergers, which are increasingly resource intensive, have augmented their respective shares in the past four years by 4% each. Although non-complex mergers make up the vast majority of cases under review (between 80-90%), their share of total reviews undertaken by the Bureau has declined substantially in the past four years. This trend, the Bureau claims, is due largely to globalization and the inherent complexities associated with multi-jurisdictional cases.

It will be interesting, now that this merger wave is sort of down, to see how resources are reallocated. As a result of that, it is certainly true that the other areas of the organization, such as the civil reviewable practices areas and conspiracy, are not nearly as well funded relative to other international comparisons. [Margaret Sanderson, Charles River Associates, 59:11:20]

29 Competition Bureau Merger Branch, *Merger Review Performance Report June 2001*, 2001.

Table 7.2
Number of Cases by Level of Complexity (%)
1997-2001

Complexity	1997-1998	1998-1999	1999-2000	2000-2001
Non-complex	68 (89%)	212 (77%)	232 (80%)	282 (81%)
Complex	8 (11%)	56 (20%)	49 (17%)	53 (15%)
Very Complex	0 (0%)	6 (2%)	8 (3%)	14 (4%)
Total	**76 (100%)**	**274 (100%)**	**289 (100%)**	**349 (100%)**

Source: Competition Bureau Mergers Branch, *Merger Review Performance Report June 2001*, 2001.

The revenue generated from fees related to merger review has been a significant but not a fully compensatory help to the Bureau's budget constraint. The Bureau estimates that revenues from pre-merger notification, advance ruling certificates and advisory opinions will be in excess of $8.4 million in 2000-2001, $7.5 million of which will be available to the Bureau. Any fees the Bureau receives in excess of $7.5 million will be credited to the government's Consolidated Revenue Fund. Given that the direct costs of merger review is estimated to be $9.5 million for 2000-2001, merger review revenues clearly fall short of cost recovery.

[T]he Bureau's workload over the past few years has greatly increased. Unfortunately, our resources have not kept pace ... In a recent survey involving five comparable competition authorities, our Bureau had the second-lowest level of funding on a per-capita basis. Our demands continue to grow, largely due to globalization and our increased mandate. Ten years ago, the great majority of cases examined by the Bureau were domestic in nature. Today, not only are there more cases, but a very large number of them have an international dimension. This is demonstrated by the increasing number of multi-jurisdictional mergers and international cartels. [Gaston Jorré, Competition Bureau, 64:09:10]

In 1997, along with fees for certain services, the Bureau established and committed itself to meet a series of service standards when reviewing mergers. These standards are: non-complex mergers, 14 days; complex mergers, 10 weeks; and very complex, 5 months. Although the Bureau has, in a given year, met these targets 100% of the time, its performance level has varied without trend since 1997. In fiscal year 2000-2001, the Bureau met the three targets 95.7%, 92.5% and 100% of the time, respectively. The average and median turnaround times for merger review have at all times been shorter than the established standard. However, in every year since 1997, a relatively small number of merger reviews has fallen well outside the target date. These poor performances appear to be isolated cases that are not the result of systemic failures, but are more likely owing to human error — errors probably committed on the part of Bureau staff and merging parties. This performance and the targeted standards, the Committee finds, are reasonable. Although

there were complaints about the merger review process made to the Committee, stakeholders had not complained about this aspect.

The Committee believes that the routine merger review procedures of the Bureau are not the cause of selected protracted merger reviews of which people complain. These reviews bog down only when the Commissioner has unresolved issues with the merger (as proposed) and intense negotiation begins for restructuring the merger proposal or when seeking a consent order, or where a contested Tribunal proceeding is going to be launched. As a consequence, the Committee sees no benefit in enshrining strict deadlines for merger review in the Act, as some commentators have suggested. Indeed, the Committee sees more harm than good coming from such Act-imposed deadlines. Given an inviolable deadline, the Bureau would be forced to work more intensively on cases that are likely to run into difficulty and breach the deadline, sacrificing resources in other reviews and therefore delaying less problematic mergers. In effect, strict or Act-imposed deadlines will compress the time distribution of completed reviews, but only at the expense of higher average turnaround times.

From the Competition Bureau's perspective, it has limited resources … the Bureau is in fact fairly strapped when it comes to resources, so it has to make responsible decisions as to how it deploys those resources. It currently has case-screening criteria that would bias its decisions in favour of bringing cases that have a broader economic impact. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 65:10:10]

Merger Enforcement Record

The combination of an unexpected and uncontrollable merger review workload, growing at rates in excess of that of staffing, with that of quick turnaround times provided by the Bureau is a situation that lends itself to the perception that vigorous enforcement of the Act may have been sacrificed. The Committee will investigate.

Table 7.3 provides the Bureau's statistical record of merger enforcement under the *Competition Act*.[30] The Bureau's entire enforcement record over the 1986-2000 timeframe is included, but the data is broken down into three four-year periods to look for trends in the statistics while overcoming a small numbers problem from which the data suffers. What is clear from the statistical record is that the past four years has involved almost as many merger

30 Data from fiscal year 2000-2001 does not include asset securitizations and is, therefore, not directly comparable.

examinations by the Bureau than that of the previous two four-year periods. Very little else can be discerned with such a high degree of confidence.

Table 7.3
Merger Enforcement Activity Under the *Competition Act* 1986-2000

Fiscal Years	1988-1992	1992-1996	1996-2000	1996-2000
Examinations Commenced	798	816	1,492	3,292
Examinations Concluded:				
As Posing No Threat Under the Act	736	776	1,443	3,094
With Monitoring	38	8	3	61
With Pre-closing Restructuring	1	-	3	6
With Post-closing Restructuring/Undertakings	6	-	10	19
With Consent Orders	3	-	5	8
Through Contested Proceedings	1	3	2	6
Abandoned by Parties as a Result of Director/Commissioner Concerns	6	12	4	27
Mergers Posing an Issue/ Examinations Concluded	6.9%	2.9%	1.8%	3.9%
Mergers Posing an Issue (Excluding Monitoring)/ Examinations Concluded	2.1%	1.9%	1.6%	2.0%
Merger Abandonment/ Mergers Posing a Threat	0.82%	1.55%	0.28%	0.87%

Source: Competition Bureau, *Annual Report of the Commissioner of Competition*, various years.

The Committee will begin its investigation by considering the perennial complaint that a contested case at the Tribunal is expensive and becoming more so. As such, one would think that the Bureau and the parties to a merger proposal would both shy away from contested proceedings and seek alternative solutions with greater frequency as the cost of a contested case rises. Although the Committee recognizes that there may be other explanations for a trend to fewer contested merger cases — particularly when we introduce qualitative information into the analysis — the data, while limited, tends to (indirectly) confirm this complaint. Four contested cases of 1,614 merger examinations were taken to the Tribunal for resolution in the two four-year periods starting in 1988 and ending in 1996. Given 1,492 merger investigations and similar vigorous enforcement, one would have expected four contested cases would have gone to the Tribunal in the 1996-2000 period; however, there were only two such cases. Therefore, the behaviours of the Commissioner and prospective merging parties suggest

that contested Tribunal cases are becoming more expensive.

Virtually all the cases that have been brought in the 15-year period since the Tribunal was created and the merger provisions were decriminalized have involved mergers that had already been consummated. At that point the merging parties had every incentive to hunker down and fight. By contrast, business people invariably have no appetite whatsoever to become involved in contested proceedings where their transaction has not yet been consummated. [Paul Crampton, Davies, Ward, Phillips & Vineberg 65:09:55]

The vast majority of mergers pose no threat, or raises no issue, under the *Competition Act*. Donald G. McFetridge reports that about 1.6% of all publicly reported mergers (7.5% of those examined) between 1986 and 1994 raised an issue under the Act.[31] According to the data in Table 7.3, the number of issues raised in merger cases has further declined in the latter half of the 1990s. When one subtracts mergers in which monitoring was the chosen enforcement response by the Commissioner — because they were never later challenged or brought back under investigation — the number of mergers that raised an issue under the Act has average only 2% of examinations undertaken by the Bureau.

The Committee finds it rather curious that, except for contested proceedings, all enforcement responses fell out of favour with the Commissioner (then the Director) in the mid-1990s. However, except for monitoring, all other enforcement responses, such as pre- and post-closing restructuring/undertakings and consent orders, have come back into favour. Moreover, what the Committee finds disturbing is that the number of mergers abandoned by their proponents as a result of the position taken by the Commissioner has declined substantially over the late 1990s. For example, 18 merger proposals were abandoned by their proponents of 1,614 merger examinations undertaken by the Bureau in the two four-year periods starting in 1988 and ending in 1996. Given 1,492 merger investigations and similar vigorous enforcement by the Commissioner, one would have expected about the same number of abandonments, 18, in the 1996-2000 period; however, there were only 4 such abandonments; less than one-quarter of what would reasonably be expected.

[W]e can review any merger, no matter what the size. Where size comes in is whether you have to notify us. … And I guess … it's a trade-off … if the world were cost-free, it would be nice to look at every merger and have notification. But given the costs imposed, there has to be some level before you create a notification process, and that's why there is a threshold for notification. [Gaston Jorré, Competition Bureau, 64:09:30]

To the Committee the data suggest one of three explanations: (1) mergers have become less problematic from a competition perspective; (2) the business community at large has in the past five years come to realize that the Commissioner is a vigorous enforcer of his Act and has increasingly acquiesced to other restrictive undertakings

31 Donald G. McFetridge, *Competition Policy Issues*, Research Paper Prepared for the Task Force on the Future of the Canadian Financial Services Sector, September 1998, p. 11.

imposed by him/her as a means of realizing their mergers; or (3) the business community has in the past five years come to realize that the Commissioner's budget is insufficient to vigorously enforce his Act and that he must acquiesce to the merging parties by seeking other non-vigorous merger enforcement methods than that of contesting them under a costly Tribunal proceedings.

It's not just the filing fee. When you notify, you have to retain counsel, you have to provide the information. You need a good adviser. [Gaston Jorré, Competition Bureau, 64:09:30]

Without qualitative information on these mergers, the Committee cannot draw definitive conclusions. However, the Committee fears that the third explanation is more likely correct and, at least in part, explains the fewer merger proposal abandonments. Somewhat paradoxically, the lack of information published on mergers that the Commissioner did not oppose as a means of protecting private and strategic market information from being made public may be providing more protection, in terms of accountability, to the Commissioner — a state of affairs that the competition law community has long complained about.

In any event, vigorous enforcement of the merger review provisions can be accomplished by providing the Bureau with adequate resources and allowing it to exercise greater selectivity in the review of mergers that are likely to pose a competition issue — recommendations that this Committee advocates.

[I]f parties to smaller transactions — mergers, for example — want to proceed with their transaction without notifying the Competition Bureau and try to fly below the radar screen, they have to take the risk that the Competition Bureau isn't going to find out about the transaction for three years, because if the Bureau does, it can bring an application to the Tribunal for up to three years and force divestiture. That's a huge risk, and business people typically do not want to assume that risk without comfort. So I find myself frequently, at any given time, having several matters on the go that involve transactions that are not above the notification thresholds, but the parties nevertheless want comfort from the Competition Bureau in the form of a no-action letter or an advance ruling certificate before they put their money on the table and proceed with the transaction. [Paul Crampton, Davies, Ward, Phillips & Vineberg, 65:10:10]

Review Thresholds

The claim that the Bureau receives insufficient funding for optimal enforcement of the Act, in particular mergers, is not new. In fact, the competition law community has made the Committee aware of this fact since it undertook its study of the *Competition Act* and its publishing of the *Interim Report*. The desire for a more complete evaluation that would consider other consequential impacts on enforcement has held the Committee from venturing beyond the call for more resources to be allocated to the Bureau. Given the concern raised in the preceding section, the Committee is now prepared to evaluate specific proposals to raise the merger review thresholds as a way of focusing scarce resources on the larger merger reviews and the enforcement of other aspects of the Act.

Since the adoption of the *Competition Act* in 1986, the parties to any significant merger — that is, a merger of a certain size as set out in the Act — are required to notify the Commissioner before closing the transaction. Although all proposed mergers may be reviewed by the Commissioner, only those mergers (i.e., asset or share acquisitions) involving more than $35 million in gross revenue from sales per annum in or from Canada, or involving more than $400 million in combined assets or sales (including affiliates) in Canada, must notify the Commissioner of the proposed transaction. The transactions threshold for amalgamations is $70 million. Both the gross sales and combined asset thresholds have remained unchanged since 1986.

One thing that would help … is the elevation of the thresholds to align them with the economic value of the threshold as it was when it first came in, in 1988. In 1988 a $35 million threshold on the transaction size was put in place. … In the meantime, the value of the dollar has eroded by more than a third, and if we were to make that adjustment today, I think it would release from the system, from the review, maybe 40% of the cases they now deal with, and would enable more people to be freed up to do other things. [Tim Kennish, Osler, Hoskin & Harcourt, 59:09:25]

Between 1986 and 2001, inflation of more than 40% (as measured by the consumer price index or CPI) has occurred. Consequently, the $35 million and $400 million thresholds have captured many more mergers than Parliament had intended when the Act was adopted. Indeed, the possible over-inclusiveness of mergers that must automatically undergo review may have been a constraint on optimal enforcement of the Act — the Bureau suggests that the gross-revenue-from-sales threshold of $35 million has been particularly binding. In other words, some resources currently devoted to merger review may be more effectively allocated to other activities, either to the review of larger mergers or to the enforcement of other provisions of the Act.

From an enforcement perspective, I would like to see increasing attention paid to other provisions of the Act, perhaps becoming a little less risk-averse from an enforcement perspective in dealing with mergers. We also heard this morning about the possibility of increasing thresholds. That might help too. [George Addy, Osler, Hoskin & Harcourt, 59:11:15]

The Bureau performed a special request for the Committee that indicates that approximately one in ten mergers examined by its Mergers Branch in the past year fell within the $35 to $50 million transactions range. This statistic, one in ten, suggests that raising the transactions threshold to $50 million would reduce the total number of merger filings by about 40 per year. Unfortunately, we were unable to find out how many of these one-in-ten mergers posed an issue under the Act. Nevertheless, given the deficiency in filing revenues to cover the direct costs of merger review and the Committee's belief that there are more pressing needs for enforcement of other activities, we believe that it is best to raise the $35 million transactions threshold to $50 million. The Committee, therefore, recommends:

26. That the Government of Canada amend section 110 of the *Competition Act* to require parties to any merger (i.e., asset or share acquisitions) involving gross revenues from sales of $50 million in or from Canada to notify the Commissioner of Competition of the transaction.

There are two thresholds. There's the transaction size and there's the party size. And we think it would be appropriate to increase the transaction size threshold, which currently is $35 million. The party-size threshold, which is $400 million, is much higher and we see increasing the first, but not the latter, roughly in line with inflation for the period since the Act came in, which takes you to about $50 million. [Gaston Jorré, Competition Bureau, 64:09:30]

Furthermore, the Committee believes there is merit in formalizing such considerations and, therefore, recommends:

27. That the Government of Canada amend the *Competition Act* to have a parliamentary review of the notification thresholds contained in sections 109 and 110 within five years and every five years thereafter to ensure optimal enforcement of the *Competition Act*.

But in looking at it historically, in countries that have had strong competition laws, like the U.S., and countries that had very weak competition laws, like Japan, they found that they didn't end up with very productive and efficient economies when they didn't foster competition and make sure those efficiencies, that productivity and efficiency, were there. So when the cases are looked at, it's not just on the basis of the consumer or the small business alone, but the Canadian economy and what benefits consumers as a whole. [Robert Russell, Borden, Ladner & Gervais, 65:10:15]

Mergers and Efficiencies

Section 96 of the *Competition Act* sets Canada's competition legislation apart from those of other countries. This section states that: "The Tribunal shall not make an order if the merger brings about gains in efficiencies that are greater than, and will offset, the effects of any prevention or lessening of competition"; this has been interpreted by some as being consistent with what is known as the "total surplus standard."

The Act also goes to considerable lengths to explain both what should and should not be included as a gain in efficiency. For example, the Act states that "the gains in efficiency" to be considered are those that "would not likely be attained if an order were made in respect of the merger"; that is, they must be merger specific. This implies that if the efficiencies could be realized in a manner that generates less anticompetitive harm than that created by the merger, then the efficiencies would not be ascribed to the merger. For example, efficiencies that could occur through internal growth or unilateral rationalization would not be ascribed to the merger. Alternatively, there may exist other cooperative means of achieving the efficiencies, such as joint ventures or a restructured merger, which would create lesser anticompetitive effects. Additionally, the efficiencies must

The analysis of efficiencies in competition law in this country is in a state of disarray, to say the least. We've had 15 years or more of toing and froing on it, and still don't know if we have anything we can work with. So if you're going to go for the section 45 reform … [focus on] what constitutes the civil test. [Donald McFetridge, Carleton University, 59:10:05]

be real and not just pecuniary; that is, the merger must bring about a real savings in resources and must not stem from greater bargaining or purchasing power that is essentially redistributive among members of society.

Within the merger review guidelines there's a part … about efficiencies which was written many years ago before Superior Propane. We have, in effect, withdrawn it. We've said that they've now been superseded by the Court of Appeal on Superior Propane and at some point once the Superior Propane case is finished we're going to have to re-write them because clearly they're not, after this litigation, a reliable guide. [Gaston Jorré, Competition Bureau, 64:10:00]

Canada is the only country known to have a competition legislation that requires the efficiencies likely to be produced by a merger to be weighed against the likely anticompetitive effects of the merger. This approach occupies the middle ground between the European Union approach, whereby the merging parties are invited to make claim to efficiencies that the Merger Task Force will consider (which introduces lobbying into the mix), and the U.S. approach, which requires efficiency gains to be so great that prices will not rise as a result of the proposed merger (the so-called "price standard"). In retrospect, this is not an unreasonable approach and, in fact, may be a strategically sound one given Canada's relatively smaller and open market economy.

[T]he efficiency defence on the merger guidelines. I think it would be an appropriate time for the committee to readdress section 96 and have a look at what it means, at how it should be applied, and provide, perhaps, some guidance from Parliament's perspective in terms of what the efficiency test is supposed to be *in a merger context.* [Jeffrey Church, University of Calgary, 59:10:20]

Although this legislative defence is unique among the industrialized countries of the world, its 15-year history has not been very hospitable to merger proponents. The Commissioner has not even once found the efficiency gains to a merger proposal sufficient to offset any lessening of substantial competition. This behaviour contrasts sharply with the Commissioner's findings of efficiency gains on many occasions pertaining to exclusive dealing and tied selling cases. Furthermore, in this same 15-year period, the Tribunal has only once decided (*Superior Propane*) and twice commented on efficiency gains (*Imperial Oil* and *Hillsdown*). The elucidations, however, have been confusing to say the least. Just when the Tribunal has come to agree with the Bureau's guidelines on the treatment of efficiencies according to the "total surplus standard" (*Superior Propane*), the Bureau abandoned its guidelines. To further confuse the issue, the Federal Court weighed in and partially overturned the Tribunal's decision in favour of expanding the strictly quantitative analysis of the "total surplus standard" to include redistributional and other qualitative effects of the merger, while neither advocating the "consumer surplus standard" or the American "price standard" approach. This Court direction had the consequence of opening the door to the Commissioner, as well as to the lone dissenting Trial judge sitting on the *Superior Propane* case, to advocate the

[W]hether the efficiencies outweigh and offset the anti-competitive effect and really, in principle, that includes everything. It includes all the anti-competitive effects and some of those are measured quantitatively but … [t]hen you have other factors which are more qualitative and you can't really measure. To give you a very simple example, how do you weigh the impact of loss of choice. If you go from having two people you can buy something from to just having one, you've clearly lost something, apart from price and it's not something you can really value but it's certainly something that has to be weighed in. [Gaston Jorré, Competition Bureau, 64, 10:00]

"consumer surplus standard."[32] Sensing that the latter standard would render section 96 virtually ineffective, the majority opinion of the Tribunal panel chose to supplement the "total surplus standard" with a calculation of what is described as the "adverse social effects" of the merger, i.e., the wealth redistributed from "poor" Canadian consumers to the shareholders of the merging parties.

The Tribunal's decision in *Superior Propane* may or may not be satisfactory; it is not clear if such precise calculations of the wealth redistributed from "poor" consumers to the shareholders of producers will be possible in future cases. Moreover, so many different interpretations of Parliament's intentions when it stated that the "*effects* of a merger that would prevent or lessen competition" must be weighed against the "gains in efficiency" suggest that more expert study is required.[33] Accordingly, the Committee recommends:

28. That the Government of Canada immediately establish an independent task force of experts to study the role that efficiencies should play in all civilly reviewable sections of the *Competition Act,* and that the report of the task force be submitted to a parliamentary committee for further study within six months of the tabling of this report.

In my view, the guidance given by that Federal Court of Appeal decision is not adequate to this task. … broadly speaking it says the Tribunal, in considering weight given to efficiencies, should apply a flexible approach, not restricted to … a total surplus approach … It takes account of diverse factors, such as the effects on small business, the possibility of creating monopolies, and perhaps income-distribution effects. [T]his Federal Court of Appeal decision is quite flawed in some respects. I also think it doesn't, whether flawed or not, give a good guide to the future conduct of competition policy. I also believe there's a danger that Canada could move from a position of being more supportive of efficiency claims in merger review than the United States … to a position where we could be less supportive of efficiency claims than the Americans. [Roger Ware, Queen's University, 65:11:30]

32 The "consumer surplus standard" weighs the gains in efficiencies against the so-called "deadweight loss" arising from the merger, as does the "total surplus standard," as well as the wealth transferred from consumers to the shareholders of the merging companies. So the "consumer surplus standard" is a more restrictive test than is the "total surplus standard."

33 In *Superior Propane*, the Tribunal also heard testimony in favour of the "price standard," the "U.S.-modified price standard," and Professor Townley's" balancing weights approach."

CHAPTER 8: REFUSAL TO DEAL

The Committee listened with concern to the testimony of the Association Québécoise des Indépendants du Pétrole (AQUIP) as it described the experience of some of their members in the Quebec petroleum market. At the outset, it is important to understand the industry is unique in that it is comprised of a handful of large companies engaged in exploration, manufacturing, wholesaling and retailing. These vertically integrated companies compete at the retail level with many small independents. This unique market structure obliges independent retailers to negotiate directly with their competitors for the supply of their main product. The *Competition Act* must, therefore, consider this state of affairs, which is peculiar to the oil sector and ensure that all companies have access to supply without discrimination.

There were shortages, and they had to set an 80% quota. We are convinced that during the 80% cut, the major company retailers were still working at full capacity, without suffering from these cuts. At those times, we had to reduce our clients' inventories. We were fortunate that these were only brief periods of a week or two in the two cases I mentioned. In the first case, the problem was caused by cold weather on the St. Lawrence River. In the second case, it was the January 1997 ice storm in Quebec. I do not know if you are aware of this, but in January 1997, there was an ice storm and supplies had to be rationed. In both cases, our supply was reduced, but we are sure that the multinationals were still running their heating oil and gas station retail networks at full capacity. [Pierre Crevier, Association Québécoise des Indépendants du Pétrole 40:16:20]

The facts presented to the Committee at its Bill C-23 hearings, if true, suggest that AQUIP might have been the victim of an anticompetitive refusal to deal.[34] Of more immediate concern to the Committee, however, was the suggestion that section 75 would not apply to prohibit this manner of conduct. AQUIP suggested that a supplier could rely on the fact that "trade terms" (market conditions) were not "usual" and the section would not apply. The Tribunal would not be able to make an order, since it could only make an order for supply on "usual" trade terms.

> We put it to you that suppliers of petroleum products would only have to illustrate that they cannot supply products because of abnormal trade conditions to stall access to the Tribunal.[35]

The Committee has carefully considered this analysis of section 75 and, with all due respect, we cannot agree with the interpretation. Reading the section as a whole, it is clear that the section was enacted not to provide a defence to unscrupulous suppliers, but rather to enable a customer to get necessary supply on the same terms as a

[34] The Committee, of course, is not a court of law. Accordingly, we do not presume to offer any conclusions on questions of fact or the application of the Act in an individual case. These are matters for the Tribunal.

[35] AQUIP, Brief to the Committee.

supplier's other customers. Moreover, for reasons set out below, we would suggest that "rationing" imposed by the supplier in response to supply shortages would fall within the definition of "terms of trade" in subsection 75(3). For that reasons, section 75 would appear to apply to ensure that a customer can get supply on the same terms as other customers, even in limited supply market conditions.

The fundamental difficulty with the AQUIP analysis is that it appears to treat the ideas "trade terms" and "market conditions" as synonyms. But as subsection 75(3) makes clear, the two ideas are quite distinct. It is a *condition* of the *market* that petroleum is in short supply, or that demand is unusually high. The terms of trade are the conditions of the *transaction*. The "terms of trade" in a transaction (such as a supply contract) may change in response to changing market conditions, that is, prices may go up or the quantities that suppliers are able to deliver might have to be reduced. Trade terms may be affected by market conditions, which necessarily implies that they are distinct concepts. AQUIP suggests that a supplier could plead "unusual *market conditions*" as a defence to section 75. But if we accept this interpretation, we would have to accept that section 75 would be of no effect in abnormal market conditions. This conclusion leads us to think that the interpretation may be incorrect.

By contrast, the Committee's interpretation finds strong support in subsection 75(3). That subsection defines "trade terms" as "terms in respect of payment, unit of purchase and reasonable technical and servicing requirements." The effect of subsection 75(3) is twofold. First, it limits the trade terms that the supplier may *impose* on the transaction. This ensures that suppliers cannot impose "unusual" trade terms (for example, rationing) as a pretext to withhold supply. Secondly, the section ensures that the customer is able to *receive* supply on the same terms as the suppliers' other customers, without being subject to any "unusual trade terms." So if other customers are receiving 100% of their orders, then all customers would be so entitled. Imposing a 20% cut on one customer, while not doing so to others would clearly be imposing an "unusual" term of trade on that customer, as the term is

contemplated in subsection 75(3). As a result, section 75 would apply and allow the Tribunal to order the resumption of supply on the same terms enjoyed by other customers.

AQUIP suggested that the phrase “usual trade terms” be deleted from section 75. This would presumably “untie the hands” of the Tribunal and give it flexibility to order supply on terms *other* than “usual” trade terms, i.e., order the supplier to accept a customer on *unusual* trade terms, e.g., pro rata shares of available supply. But again, the distinction betweens *market conditions* and *terms of trade* must be kept in mind. What AQUIP is really asking for is that the Tribunal order the supplier to continue to supply during *unusual market conditions* (e.g., supply shortages) but on the *same trade terms* (80% of usual supply using the previous example) as other customers, without discrimination.

Although the Committee does not concur that the phrase “usual trade terms” in section 75 undermines the effectiveness of the section, we do recognize that there exists another plausible interpretation of section 75, one that would lead us to the opposite conclusion, meaning that the section would *not* apply to prohibit discriminatory rationing of the type described by the AQUIP (the integrated producers supply its own retail outlets on terms more favourable than independent retailers).

Paragraph 75(1)(*d*) requires that, for the section to apply, the product must be in “ample supply.” On a plain reading, this would suggest that the section is meant to apply only in market conditions where supply is “ample,” that is at least sufficient to satisfy current demand. If this interpretation is correct, the section would not apply during periods of limited supply, and a supplier could choose to fill one customer’s order in full, while refusing another customer wholly or in part, using *discriminatory* rationing as a means of disciplining a non-integrated independent retailer.

This second interpretation is also consistent with the wording of subsection 75(3). To an ordinary observer, the term “units of purchase” might describe the manner in which the product is packaged for sale and delivery, such as in *litre* units, or in *shipping container* units, etc. In fact,

this interpretation might be more plausible than the other. Had Parliament, in drafting the legislation, wished to specify that “quantity” be included among the “terms of trade” set out in subsection 75(3), it could have drafted the legislation to that effect. Instead, Parliament used the phrase “units of purchase,” a phrase that does not clearly mean the same thing as “quantity.”

If this interpretation is correct, we would have to accept that section 75 was not meant to, and would not, apply in a market characterized by supply shortages. As such, an unscrupulous and dominant supplier could profit by the shortage to promote his own retail network and discipline independent retailers by selectively rationing their supply in a discriminatory manner. The current wording of the section might suggest that Parliament simply did not anticipate selective rationing being used in this way; or perhaps it was aware that such a practice might occur, but that it could be better addressed under the abuse of dominance provisions in section 79.

Rationing should not result in non-renewal of supply contracts on the pretext that the market situation is abnormal. On the contrary, we must ensure that abnormal market situations do not cause the elimination of efficient oil and gasoline businesses by depriving them of supply. We therefore propose that the words “on usual trade terms” be withdrawn from the bill. In this way, the new provisions would also be applicable in ordinary circumstances, where they could be particularly useful. [Pierre Crevier, Association Québécoise des Indépendants du Pétrole, 40:15:45]

The Committee is aware that the ambiguity could be resolved by simply deleting paragraph 75(1)(*d*). However, no witness raised this point and we have had no debate or analysis concerning the economic and legal implications of implementing such a change. For that reason, the Committee is reluctant to make such a recommendation. For the reasons we have set out, we believe that the more reasonable interpretation is that the section would apply in all market conditions, including markets characterized by supply shortages. Ultimately, however, the uncertainty can only be resolved in one of three ways: (1) a government amendment to clarify the application of the section; (2) the Tribunal’s judicial interpretation in the context of an application on these, or similar facts; or (3) an interpretation guideline from the Bureau.

Clearly, the preferred option is to be proactive now to clarify the application of section 75. Moreover, it is neither fair nor just that we should ask the AQUIP, or anyone else for that matter, to bear the brunt of what might turn out to be protracted and expensive litigation simply in order to clarify the law, when such a clarification is clearly

for the benefit of all. The Committee commends the AQUIP for bringing this important issue to our attention and recommends:

29. **That the Competition Bureau issue an interpretation guideline clarifying whether section 75 would apply to the circumstance where a supplier in a market characterized by supply shortages could selectively ration its available supply in such a manner as to discriminate against independent retailers.**

CONCLUSION

Canadian competition policy, as embodied in the *Competition Act* and as carried out by the Competition Bureau and the Competition Tribunal, is a modern framework for dealing with contemporary antitrust issues. The *Competition Act* generally reflects modern economic analysis, though minor modifications might be desirable. The Competition Bureau's enforcement guidelines can claim to be clear and transparent, though some fine-tuning would be helpful. The Bureau manages its current caseload well, though more resources would enable it to be a more vigilant enforcer. The Competition Tribunal has provided clear and thoughtful jurisprudence that properly embodies economic principles, though its procedures could be adjusted in order to expedite its workload and make room for more activity as a result of the granting of carefully thought out rights of private action. These were the views, and indeed the exact words, of the Committee expressed in its *Interim Report*. The Committee maintains these findings and, in this final report, has been more specific.

The Committee believes that Canada's business landscape would be served best by making conspiracies one of its highest priorities. The Committee recognizes that the Bureau has well-developed strategies and tactics already in place for detecting and pursuing both domestic and international conspiracies, but is hampered by an ineffective law — a law that is under-inclusive in its treatment of naked hard-core cartels and over-inclusive of pro-competitive strategic alliances. The Committee has, therefore, recommended that the *Competition Act* be modified to create a two-track conspiracy law, where cartels are pursued more vigorously under a stricter criminal track and strategic alliances are pursued more sensibly under a civil track through a new section. Under the existing criminal provision, the term "unduly" would be dropped to eliminate the need to litigate wasteful and irrelevant economic factors. At the same time, specific defences for efficiencies will be created, thereby reversing the onus of proof, to ensure the two tracks are kept separate. Additionally, a voluntary pre-clearance system for strategic alliances would be organized to provide guidance to the business sector seeking assurances that they will not be subject to criminal

sanctions, and thus reduce any residual “chilling effect” the law creates.

In support of realigning the enforcement priorities away from smaller mergers and back towards conspiracies, as Parliament originally intended in 1986, the Committee has recommended that more resources be allocated to the Competition Bureau and that the merger transactions notification threshold be raised from $35 million to $50 million. The Committee further recommends amending the *Competition Act* to provide automatic parliamentary reassessments of all merger notification thresholds every five years. Furthermore, the Committee recommends extending a private right of action to include abuse of dominance and expanding relief to those who have been prejudiced by reviewable conduct under exclusive dealing, tied selling, market restriction, refusal to deal, and abuse of dominance to include awards of damages and fines in order to bolster private enforcement, as a complement to public enforcement, of the Act.

The Committee makes a number of recommendations to streamline Competition Tribunal processes for disposing of cases, most notably empowering it to assess and impose damage awards and monetary penalties on those found guilty of abuse of dominance. These unbounded penalties would provide a better balance of incentives to deter abusive conduct and hopefully reduce the caseloads of the Bureau and the Tribunal. They, along with the Tribunal’s forthcoming general power to issue interim cease and desist orders in an expeditious way, as would be granted under Bill C-23, would make the existing provisions that are specific to the airline industry redundant. The airline industry-specific provisions could then be abolished to permit the return of the *Competition Act* to its traditional status as a law of general application.

The Committee further recommends the deletion of the condition of “substantial or complete control” in the abuse of dominance section of the Act. This would bring the abuse of dominance provision closer to conformity with the concept of market power as it has evolved through judicial interpretation and other sections of the Act. This amendment, along with the Competition Tribunal’s new power to assess monetary penalties under abuse of dominance, would support the decriminalization of the

anticompetitive pricing provisions — predatory pricing, vertical price maintenance, and price discrimination — as reflected in contemporary economic thinking. Criminal-like deterrence could be maintained when such behaviour constitutes an abuse of dominance, while reducing, if not eliminating, the chilling effect on pro-competitive applications of these pricing practices.

In regards to the process of merger review, the Committee recommends the establishment of an independent task force of experts for the study of the role efficiencies should play in all civilly reviewable sections of the *Competition Act*. In terms of refusal to deal, the Committee recommends that the Competition Bureau issue an interpretation guideline clarifying whether section 75 would apply to the circumstance where a supplier in a market characterized by supply shortages could selectively ration its available supply in such a manner as to discriminate against independent retailers.

In light of all of these recommended changes, the Competition Bureau must commit to rewriting its enforcement guidelines on strategic alliances, merger review and abuse of dominant position, not the least of which must be expanded to include predatory pricing, vertical price maintenance and price discrimination practices.

Finally, the Committee is convinced that these recommendations reflect the expert testimony it received; this testimony was thorough and comprehensive. A consensus was reached on most issues, allowing for specific and concrete recommendations to be made. Where a consensus was not immediately obtainable, further study was recommended. As such, we believe this report has the makings of a blueprint for a government White Paper on competition policy in Canada and the next round of amendments to the *Competition Act*.

APPENDIX A
WITNESSES

Associations and Individuals	Date	Meeting
As Individual	04/12/2001	59
George Addy, Lawyer, Osler, Hoskin & Harcourt		
A. Neil Campbell, Lawyer, McMillan Binch		
Jeffrey Church, Professor, University of Calgary		
Paul Crampton, Lawyer, Davies Ward Phillips & Vineberg		
Calvin Goldman, Lawyer, Davies, Ward & Beck		
Lawson Hunter, Lawyer, Stikeman Elliott		
Tim Kennish, Lawyer, Osler, Hoskin & Harcourt		
Donald McFetridge, Professor, Carleton University		
John Quinn, Lawyer, Blakes, Cassels & Graydon		
Thomas Ross, Professor, University of British Columbia		
Robert Russell, Lawyer, Borden Ladner Gervais		
Margaret Sanderson, Vice-President, Charles River Associates		
John Scott, President, Canadian Federation of Independent Grocers		
John Sotos, Lawyer, Sotos Associates		
Roger Ware, Professor, Queen's University		
Douglas West, Professor, University of Alberta		
Stanley Wong, Lawyer, Davis and Company		
Department of Industry	31/01/2002	64
Gaston Jorré, Acting Commissioner of Competition		
André Lafond, Deputy Commissioner of Competition, Civil Matters Branch		
R.W. McCrone, Assistant Deputy Commissioner of Competition, Criminal Matters		

Associations and Individuals	Date	Meeting
As Individual	05/02/2002	65
Paul Crampton, Lawyer, Davies Ward Phillips & Vineberg		
Tim Kennish, Lawyer, Osler, Hoskin & Harcourt		
John Rook, Lawyer, Osler, Hoskin & Harcourt		
Robert Russell, Lawyer, Borden Ladner Gervais		
Roger Ware, Professor, Queen's University		
Stanley Wong, Lawyer, Davis and Company		

REQUEST FOR GOVERNMENT RESPONSE

Pursuant to Standing Order 109, the Committee requests that the government table a comprehensive response to this report within one hundred and fifty (150) days.

A copy of the relevant Minutes of Proceedings of the Standing Committee on Industry, Science and Technology (*Meetings Nos. 59, 64 and 65 which includes this report*) is tabled.

Respectfully submitted,

Walt Lastewka, M.P.
St. Catharines

Chair

Supplementary Opinion — Canada's Competition Regime

Canadian Alliance Party
Charlie Penson
James Rajotte

Over the past two years, the Standing Committee on Industry, Science and Technology has studied the Competition Act extensively, including several private members bills, the VanDuzer report, the Committee's own interim report of June 2001, Bill C-23 and now a report from the Standing Committee. The Canadian Alliance commends the work of the members of the Standing Committee on this report and on their vigilance in studying the subject of competition policy in Canada.

Throughout these hearings, Canadian Alliance members of the Committee have consistently put forth the view that Canadian consumers and producers are best served not by a tribunal or by government interference in the marketplace, but by genuine, business-to-business competition. The focus of competition policy should not be to protect individual competitors, but should instead be to facilitate competition itself.

While the Canadian Alliance endorses the majority of this report, there are three areas where we disagree with the recommendations — specifically Chapters One, Three and Eight.

Chapter One: Competition Law cannot replace competition

Chapter One recommends that conspiracy-related crimes against competition (i.e. price fixing) should be one of the most important concerns for the Competition Bureau. It also supports the idea that there should be no special rules for specific industries within overarching framework law.

In the opinion of the Canadian Alliance, the underlying theme of market regulation contained in Chapter One is fundamentally flawed. The Liberal party's policy of tinkering with competition law and regulating the market place cannot replace the need for a healthy business environment.

The report acknowledges the monopoly-creating distortion of government policies, such as foreign ownership rules, which act as barriers to entry in the airline and retail book industries. Canada's small domestic market and large geography are usually used as justification for regulation, but the Canadian Alliance believes that these problems have been compounded by the Liberal government's approach to industrial policy. There are too many sectors in the Canadian economy that escape market forces — telecommunications, wheat marketing, and transportation being examples. It

is far better to have a proper business and tax environment for many competitors than regulation for a few.

Direct government interference in these sectors has resulted in reduced competition. The Liberal's reaction is not to reduce regulations, but to compensate by amending the Competition Act. This approach compromises competition law and does not facilitate competition. For example, the government has amended the *Competition Act* to regulate the airline industry using cease and desist powers, monetary penalties and a consumer complaints referee. Yet, all these changes cannot discipline Air Canada like a competitive marketplace would. In addition, framework law such as the *Competition Act* is not the right place to regulate industry.

There is a belief that certain industries must be protected from foreign ownership or interference, but at what cost to the Canadian consumer? The National Energy Program made no sense for the Canadian oil industry and the Canadian Alliance suggests that mandated national ownership is not advantageous for other industries. Even if the situation could be corrected completely by the *Competition Act*, which is doubtful, it would certainly cost much more for the same result a market solution would produce.

In recent years, the Competition Commissioner has approved large-scale mergers in the airline or retail book industry, with caveats that certain assets be sold to other interests. In both cases, the deadlines passed with no prospective buyers coming forward due to government-imposed domestic-ownership rules. The end result in both industries has been a more concentrated monopoly and less choice for the Canadian consumer.

The Canadian Alliance therefore recommends:

The Liberal government and the Minister of Industry should designate business-to-business competition as one of its highest priorities by making a concerted effort to reduce regulation and government interference in the marketplace.

Chapter Three — Delays at the Competition Tribunal

Chapter Three attempts to deal with difficulties at the Competition Tribunal. The Canadian Alliance would like to call attention to undue delays in reaching a final decision. The abuse of dominance case that WestJet and now defunct Canada 3000 (CanJet) brought against Air Canada case is certainly an example where justice delayed is justice denied. This case will play a part in determining the future of the Canadian airline industry, and yet Air Canada has managed to secure two six-month adjournments. At present, the case is scheduled to resume in Fall 2002 — a full two years after the Air Canada seat sale at issue had taken place.

The Canadian Alliance is very concerned about these developments. Not only is Air Canada not being held accountable for its actions, but much needed clarity on competition rules has been put off again. Continuing ambiguity discourages new entrants into the market. Delays in the process mean that it is very difficult to entice investors to put money into new passenger air carriers.

The Canadian Alliance therefore recommends:

That the Competition Tribunal should increase its efforts to ensure cases brought before it are heard in a timely manner.

Chapter Eight — Vertical Integration in the Oil and Gas Retail Industries.

Chapter Eight is particularly troublesome because the experts convened in preparation for this report did not raise the relationship between vertically integrated corporations and their independent retailers. Indeed, this Chapter is essentially based on one association's point of view and from testimony delivered in October 2001 when the association appeared before the Committee's study of Bill C-23.

The inclusion of this issue in the Committee's report serves to highlight the Liberal government's predisposition to politicize competition law and policy.

It is the opinion of Canadian Alliance members of the Committee that the recommendation to clarify the Bureau's guidelines with respect to Section 75 is not constructive. There are times when scarcity methods of allocation are necessary and retailers should not be able to use private access to leverage their contracts. The Canadian Alliance believes that the Competition Act should not interfere with contract law and these types of complaints would be better dealt with under Section 79 (abuse of dominance).

NDP Dissenting Opinion
Bev Desjarlais, MP Churchill, NDP Industry Critic

Introduction

The Majority Report focuses exclusively on fine-tuning Canada's existing competition laws and makes recommendations to that effect. What the Committee has failed to recognize is that competition laws, while important, are not the be all and end all of competition policy.

Due to its narrow focus, the Majority Report does not consider the implications of other government policies on Canada's overall competitive framework. Tinkering with competition laws, as this Report recommends, will have little impact on competition in Canada without addressing the broader policies government policies that undermine competitive markets.

The Social Benefits of Competitive Markets

It is worth underlining that social democrats support the establishment of competitive markets as a fundamental social good unto itself. Our history in the twentieth century has proven, beyond any doubt, that competitive market economies deliver better, more prosperous, more comfortable and fulfilling lives for citizens than any of the anti-market alternatives. Competitive markets maximize our prosperity by encouraging entrepreneurship and efficiency and by widening consumer choice.

The Liberals and the other right-wing parties talk incessantly about the benefits of markets. Unfortunately, all this talk is merely a smokescreen for policies that distort markets and promote monopoly at the expense of competition.

Perfect Competition

It should go without saying that competition is the basis of a properly functioning market. Economists evaluate the competitiveness of a given market against an idealized model of perfect competition. Perfect competition requires: 1) that buyers and sellers have all the information they need to make informed choices; 2) that there are enough buyers and sellers to prevent any one actor from influencing the market; 3) homogeneous products; 4) that there are no barriers to market entry; and 5) perfect mobility of production factors.

Eliminating Distortion

In real life, markets never achieve the ideals of perfect competition. Any real life factor that interferes with one of the five assumptions of perfect competition is a market distortion. The fewer distortions there are in a given market, the more its outcomes benefit society. Conversely, when markets are distorted, the benefits of competition are reduced or negated. Thus, the object of our government's competition policy should be to eliminate and/or mitigate market distortions.

Regulation vs Distortion: How the Right Distorts Competition

The political right has built a false mythology about markets. This mythology holds that all government regulation is, by definition, a market distortion. It follows from this that removing regulations removes distortions and moves markets closer to perfect competition. The Liberal government uses this ideological approach to justify deregulating everything they possibly can.

The problem with this approach is that regulation is not, by definition, a market distortion. Sometimes it is, but most government regulations actually promote competition by reducing market distortions, thereby making markets more competitive. This is due to the fact that, in the real world, markets have built in distortions. Effective regulations eliminate or mitigate these distortions and make markets more competitive.

Real Life vs Ideology: The Repeated Failures of Deregulation

Without sufficient regulation to eliminate or mitigate distortions, many markets inevitably become, to a greater or lesser degree, anti-competitive, inefficient and harmful to consumer choice. The kinds of markets that are prone to these outcomes when deregulated are those that, structurally, are the furthest from the ideal of perfect competition. The more distortions a market has in its unregulated state, the more anti-competitive it is in the absence of corrective regulations.

In our experience with deregulation in North America, markets with severe barriers to entry and limited numbers of sellers have consistently been the most failure prone when deregulated. Examples of such industries include the airline industry, electricity and health care.

Canada's airline industry is a striking example of an industry in which government deregulation has increased market distortion, leading to a single-airline monopoly. This is because the airline industry is, structurally, so far from the ideal of perfect competition that, in the absence of regulations to correct its distortions, it rapidly trends toward the elimination of competition. It has enormous barriers to market entry and far too few sellers to prevent market manipulation. For consumers, the end result of deregulation

has been the elimination of choice and higher air fares, the opposite of what the government promised when it deregulated the industry.

Outcomes have been similarly negative in the electricity and health care sectors. Jurisdictions that have deregulated electricity markets, such as California and Alberta, have experienced monopolistic price manipulation and, in the case of California, deliberate manipulation of energy supplies that led to blackouts.

America's supposedly free market health care system is, in fact, demonstrably less efficient than Canada's highly regulated system. The American system is also highly intrusive into personal medical decisions. Private insurance companies routinely second guess treatments and prevent Americans from switching doctors. Thus, Canada's highly regulated health care system delivers the benefits of competition, greater efficiency and choice, better than America's less regulated model.

When confronted with the real life failures of their mythology, the Liberal government and others on the political right respond with a convenient tautology. Any time deregulation fails, they simply claim that they did not deregulate enough and use this to justify further deregulation that further distorts the market. This refusal or inability to grasp when cold hard reality contradicts theory is classic ideological behaviour.

How Regulation Promotes Competition

All markets have built in distortions that reduce or negate the benefits of competition. Economists recognize that perfect competition is an unattainable ideal. Regulation promotes competition by eliminating or mitigating market distortions.

For an example of how regulation eliminates market distortion, look no further than your local supermarket. The government imposes very strict labelling regulations on most supermarket products to make sure consumers have information on nutritional factors and price per unit. Since consumer information is one of the requirements of perfect competition, these regulations eliminate a market distortion and help the market function more efficiently. The world is full of similar examples of regulations that expedite commerce, like government regulations of weights and measures and enforcement of standards and labelling on other products, like textiles and consumer durables.

Regulations can also mitigate market distortions to reduce their harmful effects on competition. Let us return to the example of the airline industry. No regulations can eliminate the barriers to market entry, such as the prohibitive start-up costs and the limitations of the supporting infrastructure like airports and air traffic control resources. However, more effective regulations to prevent the Air Canada monopoly from using its market power to systematically destroy all competition could at least mitigate the distortions inherent in this market.

New Democrats, New Vision for Competition

Canada's New Democrats propose a new approach to competition policy, beginning from the assertion that government has a positive role to play in promoting competition by eliminating and mitigating market distortions. This would mean a departure from the dominant mythology that government regulation is automatically distorting.

While New Democrats do not oppose the minor tinkering proposed by the Majority Report, we consider the report inadequate because it is constrained by its narrow focus. There is no discussion of, for example, the role that consumer rights play in competition policy. Well-informed consumers are a necessary part of a healthy competitive market, and one of the requirements for perfect competition, yet the Liberal government continues to ignore growing public demands for more information on the labels of consumer products.

New Democrats have been at the forefront of campaigns for mandatory labelling of genetically modified foods and changes to the Textile Labelling Act that would tell Canadian consumers whether or not the clothes they buy are produced with Third World child labour. By refusing to make this information available to consumers, the Liberal government is deliberately protecting the market distortions created by this lack of information. In so doing, they contradict their stated support for competitive markets and expose their real agenda — to protect companies with existing market power at the expense of new entrepreneurs and competitors who would offer the public a wider range of choices.

Labelling is just one example of an area where the Liberal government's ideologically driven antipathy to regulation results in less competition and choice. Another example is their headlong rush to deregulate industries, like the airline industry, which contain major structural distortions that require regulation to prevent natural monopolies from taking hold. The result of their "deregulate everything" approach is less competition, the rewarding of inefficiency, less choice and higher prices for consumers. The only winners are companies that already have market power, which are free to abuse their dominant market positions. The losers are consumers, smaller and newer businesses, entrepreneurs and society as whole, which loses out on the benefits of a dynamic and innovative economy.

When New Democrats challenge the Liberal government's ideological refusal to promote competition in the economy, the government typically responds with unfounded accusations that the NDP is an enemy of business and enterprise. Nothing could be further from the truth. We do not call for massive government intervention in the economy, but rather a balanced approach focused on promoting healthy competitive markets. Indeed, the real enemies of enterprise are the anti-competitive policies of the government that promote and protect inefficient monopolies, gouge consumers and squeeze the innovation out of our economy by blocking competition from newer, smaller and more dynamic businesses.

MINUTES OF PROCEEDINGS

Tuesday, April 9, 2002
(*Meeting No. 74*)

The Standing Committee on Industry, Science and Technology met *in camera* at 9:15 a.m. this day, in Room 308, West Block, the Chair, Walt Lastewka, presiding.

Members of the Committee present: Larry Bagnell, Stéphane Bergeron, Walt Lastewka, Serge Marcil, Dan McTeague, James Rajotte, Andy Savoy and Paddy Torsney.

Acting Member present: Cheryl Gallant for Charlie Penson.

In attendance: *From the Library of Parliament*: Dan Shaw and Geoffrey P. Kieley, Research Officers.

Pursuant to the Committee's mandate under Standing Order 108(2), the Committee resumed consideration of the Competition Law and Policy *(See Minutes of Proceedings, Tuesday, December 4th, 2001, Meeting No. 59)*.

It was agreed, — That pursuant to Standing Order 109, the Committee request that the Government table a comprehensive response to this report within one hundred fifty (150) days.

It was agreed, — That the Chair be authorized to make such typographical and editorial changes as may be necessary without changing the substance of the Draft Report to the House.

It was agreed, — That the Draft Report (as amended) be concurred in.

Ordered, — That the Chair present the Report (as amended) to the House at the earliest possible opportunity.

It was agreed, — That in addition to the 550 copies printed by the House, an additional 1000 copies of the Report be printed in a tumble format.

It was agreed, — That a News Release be issued.

It was agreed, — That a News Conference be held upon presentation of the Report.

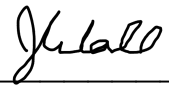
It was agreed, — That the Committee express its appreciation for the professionalism and excellent work of Daniel Shaw and Geoffrey Kieley, Research Officers, Library of Parliament and to Norm Radford, Clerk Committees Directorate.

At 11:00 a.m., the Committee adjourned to the call of the Chair.

Normand Radford
Clerk of the Committee

Exhibit “S8”

This is Exhibit “S8” referred to in the Affidavit of Emily Seaby, sworn before me this 26th day of July, 2024.



A Commissioner for Taking Affidavits, etc.
Jon Wall

356 PUBLIC

ANNUAL REPORT 2022

Patented Medicine Prices Review Board

Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

Canada

The Patented Medicine Prices Review Board
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STATISTICAL HIGHLIGHTS 2022

PRICE REVIEW MANDATE

- 1,138 patented medicines for human use were reported to the PMPRB, including 69 new medicines.
- 8 Voluntary Compliance Undertakings (VCUs) were accepted as of December 31, 2022.
- More than $31.2 million in excess revenues and potential excess revenues were offset by way of payments to the Government of Canada through VCUs, settlements, and Board Orders.

REPORTING MANDATE

SALES TRENDS:

- Sales of patented medicines in Canada were $18.4 billion in 2022, an increase of 5.7% from the previous year.
- Patented medicines accounted for approximately 49.0% of the sales of all medicines in Canada in 2022.

PRICE TRENDS:

- The Consumer Price Index rose by 6.8%, while the national average transaction price for patented medicines increased by 0.8%.
- Canadian list price ratios rose from third to second highest among the 31 Organisation for Economic Co-operation and Development (OECD) countries, behind only the US.

RESEARCH AND DEVELOPMENT (R&D):

R&D-TO-SALES RATIOS DECREASED IN 2022:

- 3.1% for all rights holders, a decrease from 3.4% in 2021.
- 3.2% for Innovative Medicines Canada members, a decrease from 3.5% in 2021.

R&D EXPENDITURES:

- $914.0 million in total R&D expenditures were reported by rights holders in Canada, a decrease of 1.0% over 2021.
- $748.6 million in R&D expenditures were reported by Innovative Medicines Canada members, an increase of 1.7% over 2021.

24 November 2023

The Honourable Mark Holland, P.C., M.P.
Minister of Health
House of Commons
Ottawa, Ontario
K1A 0A6

Dear Minister:

I have the pleasure to present to you, in accordance with sections 89 and 100 of the *Patent Act*, the Annual Report of the Patented Medicine Prices Review Board for the year ended December 31, 2022.

Yours very truly,

Thomas J. Digby
Chairperson

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

Continued on next page...

LIST OF FIGURES
...CONTINUED

CHAIRPERSON'S MESSAGE

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body established by Parliament in 1987 under the *Patent Act* (the Act). The PMPRB's mandate is to protect and inform Canadians by ensuring that the prices of patented medicines sold in Canada are not excessive and by reporting on pharmaceutical trends.

With the coming-into-force of Health Canada's amendments to the *Patented Medicines Regulations* on July 1, 2022, the PMPRB has been developing new Guidelines to implement these regulatory changes into the Board's operations. The Board acknowledges these regulatory changes reflect important court decisions, including by the Quebec Court of Appeal [*Merck Canada Inc c Procureur général du Canada*, 2022 QCA 240] and the Federal Court of Appeal [*Alexion Pharmaceuticals v Canada (Attorney General)*, 2021 FCA 157; *Innovative Medicines Canada v Canada (Attorney General)*, 2022 FCA 210].

The regular operations of the Board have continued to provide value for Canadian payers. In the fall of 2022, the Board's Hearing Panel issued a decision that found that the price of Procysbi (cysteamine bitartrate) was excessive under section 83 and 85 of the *Patent Act*, directing Horizon Therapeutics Canada to pay just over $22 million to the Receiver General of Canada. This brought the total excess revenues collected through Voluntary Compliance Undertakings (VCUs), settlements, and Board Orders in 2022 to more than $31 million.

Analytical studies conducted through the PMPRB's reporting mandate under the banner of the National Prescription Drug Utilization Information System (NPDUIS) initiative continue to show the vast pressures stemming from the increased use of higher-cost medicines in Canada. Over the last five years, sales of patented medicines have grown by an average of 1.8% per year, reaching $18.4 billion in 2022. High-cost medicines now account for 57.5% of these sales. In 2022 the 20 top-selling patented medicines in Canada, which accounted for 37.7% of total patented medicine sales, had a median treatment cost of $21,345, compared to just $803 in 2013.

Significantly, in 2022, the average list price for medicines in Canada rose from third to second highest among the 31 countries of the Organisation for Economic Co-operation and Development (OECD), behind only the US. The average list price is above all our PMPRB11 comparator countries, as may be seen in the average foreign-to-Canadian price ratios calculated using external data. It is acknowledged that the new *Patented Medicines Regulations* took effect at the mid-point of 2022, and are not expected to impact average list price ratios until later reporting cycles.

In early 2023, Douglas Clark, the PMPRB's longtime Executive Director, announced his retirement after nearly a decade with the organization. On behalf of the PMPRB, I offer our thanks for his years of dedication and commitment. As we move forward under new leadership, the PMPRB remains committed to serving Canadians through the responsible and efficient use of our regulatory powers, in collaboration with and in support of our many stakeholders and partners in the Canadian healthcare system.

Thomas J. Digby
Chairperson

ABOUT THE PATENTED MEDICINE PRICES REVIEW BOARD:

ACTING IN THE INTEREST OF CANADIANS

The Patented Medicine Prices Review Board (PMPRB) is an independent, quasi-judicial body established by Parliament in 1987 under the *Patent Act* (Act).

The PMPRB is a quasi-judicial administrative agency with a dual price review and reporting mandate. Through its price review mandate, it ensures that the prices of patented medicines sold in Canada are not excessive. The PMPRB also reports on trends in pharmaceutical sales and pricing for all medicines and on research and development (R&D) spending by rights holders. In addition, at the request of the Minister of Health, pursuant to section 90 of the Act, the PMPRB conducts critical analyses of price, utilization, and cost trends for patented and non-patented prescription medicines under the National Drug Utilization Information System (NPDUIS) initiative. Its reporting mandate provides pharmaceutical payers and policy makers with information to make rational, evidence-based reimbursement and pricing decisions.

The PMPRB is part of the Health Portfolio, which includes Health Canada, the Public Health Agency of Canada, the Canadian Institutes of Health Research, and the Canadian Food Inspection Agency. The Health Portfolio supports the Minister of Health in maintaining and improving the health of Canadians.

OUR MISSION

The PMPRB is a respected public agency that makes a unique and valued contribution to sustainable spending on pharmaceuticals in Canada by:

- Acting as an effective check on the prices of patented medicines and intervening where the Board determines a price to be excessive; and
- Providing stakeholders with price, cost, and utilization information to help them make timely and knowledgeable pricing, purchasing, and reimbursement decisions.

PROTECTING CONSUMERS IN A COMPLEX MARKETPLACE

(CADTH) Canadian Agency for Drugs and Technologies in Health; (INESSS) Institut national d'excellence en santé et en services sociaux; (CDR) Common Drug Review; (pCODR) pan-Canadian Oncology Drug Review; and (pCPA) pan-Canadian Pharmaceutical Alliance

Data source: PMPRB

Although part of the Health Portfolio, because of its quasi-judicial responsibilities, the PMPRB carries out its mandate at arm's length from the Minister of Health, who is responsible for the sections of the Act pertaining to the PMPRB. The PMPRB also operates independently of other healthcare-related bodies, such as:

- Health Canada, which approves medicines for marketing in Canada based on their safety, efficacy, and quality;
- federal, provincial, and territorial (F/P/T) public drug plans, working collectively as the pCPA, which approve the listing of medicines on their respective formularies for reimbursement purposes; and
- the Common Drug Review and pan-Canadian Oncology Drug Review, administered by the CADTH, which recommend which new medicines should qualify for reimbursement by the pCPA. In Quebec, this evaluation process is conducted by INESSS.

The PMPRB is composed of up to five Board Members, Governor-in-Council appointees who are assisted in their work by public servants (Staff).

JURISDICTION

PRICE REVIEW

The PMPRB reviews the price at which rights holders (companies) sell their products to wholesalers, hospitals, pharmacies and other large distributors to ensure that this price is not excessive. This price is sometimes also known as the "factory gate" (ex-factory) price. The PMPRB does not review the prices of non-patented medicines (e.g., generics).

The PMPRB's jurisdiction is not limited to medicines for which the patent is for the active ingredient or for the specific formulation(s) or uses the rights holder sells the medicine for in Canada. Rather, its jurisdiction also covers medicines for which a patent "pertains", including patents for manufacturing processes, delivery systems or dosage forms, indications/use, and any formulations.

1,138 PATENTED MEDICINES

were reported to the PMPRB in 2022.

The Act requires rights holders (which include any parties who benefit from patents regardless of whether they are owners or licensees under those patents and regardless of whether they operate in the "brand" or "generic" sector of the market) to inform the PMPRB of their intention to sell a new patented medicine. Upon the sale of a new patented medicine, rights holders are required to file price and sales information at introduction and, thereafter, until all patents pertaining have expired. Rights holders are not required to obtain approval of the price to be able to market their medicines. However, the Act requires the PMPRB to ensure that the prices of patented medicines sold in Canada are not excessive.

Staff review the prices that rights holders charge for each individual strength and form of a patented medicine. If the price of a patented medicine appears to be potentially excessive, the rights holder may volunteer to lower its price and/or refund its potential excess revenues through a Voluntary Compliance Undertaking (VCU). If this fails, the Chairperson may consider whether a hearing on the matter is in the public interest. At the hearing, a panel composed of Board members acts as a neutral arbiter between Staff and the rights holder. If a Hearing Panel concludes, after hearing all of the evidence in light of the factors set out in section 85 of the Act, that the price of a patented medicine is/was excessive in any market, it can order the maximum ceiling price to be reduced to a non-excessive level. It can also order a rights holder to make a monetary payment to the Government of Canada to offset the excess revenues earned and, in cases where the panel determines there has been a policy of excessive pricing, it can double the amount of the monetary payment.

REPORTING

As required by the Act, the PMPRB reports annually to Parliament through the Minister of Health on its price review activities, the prices of patented medicines and price trends of all prescription medicines, and on the R&D expenditures reported by pharmaceutical rights holders.

In addition, as a result of an agreement by the F/P/T Ministers of Health in 2001, and at the request of the Minister of Health, pursuant to section 90 of the Act, the PMPRB conducts critical analyses of price, utilization, and cost trends for patented and non-patented prescription medicines under the National Prescription Drug Utilization Information System (NPDUIS). The PMPRB publishes the results of NPDUIS analyses in the form of reports, posters, presentations, briefs, and chartbooks. This program provides F/P/T governments and other interested stakeholders with a centralized, objective, and credible source of information on pharmaceutical trends.

The PMPRB also hosts various forums, such as webinars, research forums, and information sessions with academics and policy experts to discuss and disseminate research on emerging areas for study on pharmaceutical trends in Canada and internationally.

COMMUNICATIONS AND OUTREACH

The PMPRB takes a proactive and plain-language approach to its external communication activities. This includes targeted social media campaigns and more conventional (e.g., email) engagement with domestic, international, and specialized news media. The PMPRB is actively pursuing additional opportunities to leverage new and emerging media to communicate with its stakeholders and the Canadian public.

The PMPRB recognizes the importance of openness and transparency as we continue to work on modernizing the way we carry out our mandate. We communicate regularly, through various channels, about our progress, including projected timelines, and key milestones. Engagement with stakeholders will remain a central part of our multi-faceted communications approach. Reporting on our progress helps ensure we remain focused on delivering results.

GOVERNANCE

The Board consists of not more than five members who serve on a part-time basis. Board members, including a Chairperson and a Vice-Chairperson, are appointed by the Governor-in-Council. The Chairperson, designated under the Act as the Chief Executive Officer of the PMPRB, has the authority and responsibility to supervise and direct its work. By law, the Vice-Chairperson exercises all the powers and functions of the Chairperson when the Chairperson is absent or incapacitated, or when the office of the Chairperson is vacant.

The members of the Board, including the Chairperson, are collectively responsible for implementing the applicable provisions of the Act. Together, they establish the guidelines, rules, by-laws, and other policies of the PMPRB provided for by the Act (section 96) and consult, as necessary, with stakeholders including provincial and territorial Ministers of Health, representatives of consumer groups, the pharmaceutical industry, and others.

MEMBERS OF THE BOARD

Chairperson

Thomas J. Digby

Thomas Digby was appointed Chairperson of the Board on February 1, 2023.

Thomas Digby is a lawyer with more than 25 years' experience in Canadian and US intellectual property (IP) law, in the field of pharmaceuticals. He has worked closely with diverse biotech start-ups, their venture investors, and, for 10 years, with the global pharmaceutical leader, Novartis.

Thomas attended Queen's University (BSc [Hons], 1987) and Dalhousie University (MSc [Biochem], 1990), and graduated from Dalhousie Law School (now Schulich School of Law) (JD, 1992). He is licensed to practice in both Canada and the United States (Ontario [1994], New York [1995], Massachusetts [1995], British Columbia [1998]). He was formerly registered to practice before the United States Patent and Trademark Office (2005–2012).

After articling with Blakes in Toronto, Thomas worked with a variety of biotech start-ups including Visible Genetics, Inex Pharmaceuticals, and Xenon Pharmaceuticals. At Inex, he provided IP strategy for the discovery efforts that led to the lipid-nanoparticle delivery system used in current COVID mRNA vaccines.

Thomas joined Novartis at its research headquarters in Cambridge MA (2005–2012), and later moved to the head office in Basel, Switzerland (2012–2015). At Novartis, he specialized in global transactions, led a multi-country IP enforcement program, supported the global tax team and the Novartis Venture Fund, and was regularly involved with the IP strategy of the generic (Sandoz) and innovator (Novartis) divisions.

In 2016, Thomas returned to Vancouver with his family, where he is a sole practitioner supporting the IP strategy of a small number of Canadian and US biotech clients. Among other community roles, he is a Commissioner of the Vancouver Board of Parks and Recreation.

Vice-Chairperson

Anie Perrault

Anie Perrault was appointed Vice-Chairperson of the Board on August 15, 2023.

Ms. Anie Perrault is a lawyer by training (University of Ottawa – 1992; Barreau 1993) with more than 30 years of professional experience in the public and private sectors. Her career has focused on communications and public affairs related to genomic research and biotechnology and she has held several strategic positions at a national level in this field. She was Director General of BIOQuébec from 2013 to 2022 and Vice President, Communications of Genome Canada from 2001 to 2006.

Named Sun Life Leadership – Exceptional Woman finalist in the prestigious Les Mercuriades 2021 competition, Ms. Perrault is also an accredited mediator from the Institute of Mediation and Arbitration of Quebec. Ms. Perrault was a Member (administrative judge) of the Canadian Human Rights Tribunal from 2015 to 2021, and continues to act as a mediator there today.

In 2013, Ms. Perrault received the title of Certified Corporate Administrator from the College of Corporate Administrators at Laval University. She is president of the board of directors of Génome Québec. She has also served on the board of directors of ACCESSA since 2020. She was a member of the boards of the Jeanne-Mance Foundation from 2016 to 2022, Loto-Québec from 2011 to 2021 and the University of Sherbrooke from 2016 to 2019.

Member

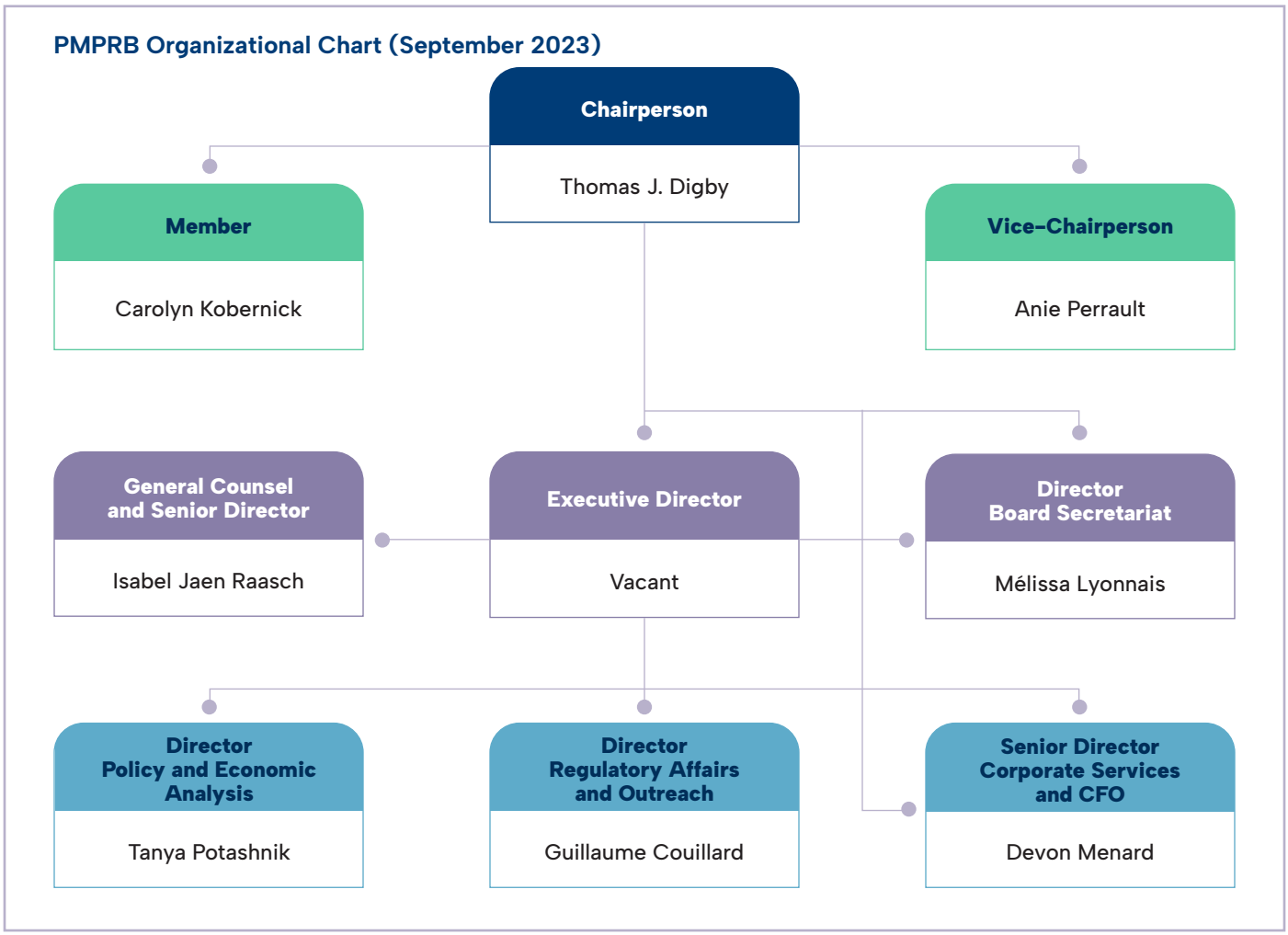
Carolyn Kobernick,
B.C.L., LL.B.

Carolyn Kobernick was appointed Member of the Board on June 13, 2014.

Ms. Kobernick is a lawyer and former public servant. Prior to her retirement in 2013, Ms. Kobernick had been Assistant Deputy Minister of Public Law for the Department of Justice since 2006. As principal counsel to the Minister of Justice and Attorney General of Canada, Ms. Kobernick was instrumental in the development and delivery of policy for the Department of Justice. In addition to identifying key strategic, legal, and operational matters, she tackled cross-cutting national issues as the liaison between the Department of Justice and other government organizations.

Ms. Kobernick holds a B.C.L. and LL.B. from McGill University and is a member of the bar of Ontario. In 2012 she obtained a Certificate in Adjudication for Administrative Agencies, Boards and Tribunals from the Osgoode Hall Law School and the Society of Ontario Adjudicators and Regulators.

ORGANIZATIONAL STRUCTURE AND STAFF



Executive Director

The Executive Director is responsible for advising the Board and for the leadership and management of Staff.

Regulatory Affairs and Outreach

The Regulatory Affairs and Outreach Branch reviews the prices of patented medicines sold in Canada; ensures that rights holders are fulfilling their filing obligations; encourages rights holders to comply voluntarily with the PMPRB's Guidelines; implements related policies; and investigates complaints into the prices of patented medicines.

Policy and Economic Analysis

The Policy and Economic Analysis Branch develops policy and strategic advice; leads stakeholder consultations and makes recommendations on possible amendments to the PMPRB's Guidelines; conducts research and analysis on the prices of medicines, pharmaceutical market developments, and R&D trends; and publishes studies aimed at providing F/P/T governments and other interested stakeholders with centralized, objective, and credible information in support of evidence-based policy.

Corporate Services

The Corporate Services Branch provides advice and services in relation to human resources management; facilities; procurement; health, safety, and security; information technology; and information management. It coordinates activities pursuant to the *Access to Information Act* and the *Privacy Act*, and is responsible for strategic planning and reporting. It is also responsible for financial planning and reporting, accounting operations, audit and evaluation, and liaising with federal central agencies on these topics.

Board Secretariat

The Board Secretariat manages the Board's meeting and hearing processes, including the official record of proceedings.

General Counsel

The General Counsel advises the PMPRB on legal matters, leads the legal team representing Staff in proceedings before the Board, and liaises with counsel for the Attorney General in PMPRB-related proceedings before federal and provincial courts.

BUDGET

In 2022-23, the PMPRB had a budget of $17.0 million and an approved staff level of 84 full-time equivalent employees.

TABLE 1. BUDGET AND STAFFING

	2021-22	2022-23	2023-24
Budget*	$18,892,322	$17,003,213	$17,093,674
Salaries and employee benefits	$10,175,540	$10,164,617	$10,257,961
Operating	$2,510,296	$2,375,235	$2,372,352
Special Purpose Allotment†	$6,206,486	$4,463,361	$4,463,361
Full Time Employees (FTEs)	85	84	81

* Budget amounts are based on the Main Estimates.

† The Special Purpose Allotment is reserved strictly for external costs of public hearings (legal counsel, expert witnesses, etc.). Unspent funds are returned to the Consolidated Revenue Fund.

MONITORING PRICES OF PATENTED MEDICINES:

INFORMING ON PMPRB PRICE REVIEW ACTIVITIES

Medical advancements have introduced many innovative new medicines to the Canadian marketplace to improve existing treatments and to treat conditions that previously had no pharmaceutical therapy. However, many of these new medicines come at a very high cost. Since 1987, pharmaceutical costs in Canada have grown at an average annual rate of 6.6%,[1] outpacing most other health care costs and growing at approximately three times the rate of inflation over the same period. At 13.6 % of total health care spending, pharmaceutical expenditure is level with spending on physicians.[2] In 2021, about 1 in 5 Canadians reported having no prescription medicine coverage while many more were under-insured or faced high deductibles or co-pays. As a result, almost 1 in 10 Canadians had to forego filling a prescription for reasons related to cost.[3]

The PMPRB protects the interests of Canadians by ensuring that the prices of patented medicines sold in Canada are not excessive. It does this by reviewing the prices that rights holders charge for each individual patented medicine and by ensuring that rights holders reduce their prices and pay back excess revenues, where appropriate.

REPORTING REQUIREMENTS

By law, rights holders must file information about the sale of their medicines in Canada. The Act and the ***Patented Medicines Regulations*** (Regulations) set out the information required and Staff reviews pricing information on an ongoing basis until all relevant patents have expired. When the review of the information filed by rights holders suggests that the price of a patented medicine may be excessive, the rights holder is given an opportunity to voluntarily lower its prices and/or refund its potential excess revenues through a Voluntary Compliance Undertaking (VCU). If the rights holder chooses not to submit a VCU, the Chairperson may consider whether a hearing on the matter is in the public interest. If such a hearing is held before a panel composed of Board members ("Hearing Panel") and that Hearing Panel concludes, after hearing all of the evidence in light of the factors set out in section 85 of the Act, that the patented medicine was priced excessively in any market, an order may be issued to the rights holder requiring that (1) the maximum ceiling price of the medicine be reduced to a non-excessive level; and/or (2) that measures be taken to offset any excess revenues that may have been earned through sales of the patented medicine at an excessive price.

Amending Regulations to the *Patent Act* were published in the **Canada Gazette, Part II**, moving forward with the implementation of a new basket of comparator countries and reduced reporting requirements for those medicines at lowest risk of excessive pricing, which came into force on July 1, 2022. The composition of reference countries moved from the previous seven (PMPRB7) to a broader group of eleven countries (PMPRB11) by removing the United States and Switzerland and adding six others (Australia, Belgium, Japan, Netherlands, Norway, and Spain).

The ***Compendium of Policies, Guidelines and Procedures*** details price tests and triage mechanisms used by Staff up to July 1, 2022, when it reviewed and investigated the prices of patented medicines. The Board is in the process of developing new Guidelines and until new Guidelines are implemented, **Interim Guidance** issued by the Board on August 18, 2022, is in operation. Guidelines are not binding and are developed in consultation with stakeholders, including the provincial and territorial Ministers of Health, consumer groups, and the pharmaceutical industry. Copies of the Act, the Regulations, and the Guidelines are available on the **PMPRB's website**.

FAILURE TO REPORT

Access to timely and accurate information regarding the sale of patented medicines is necessary for the PMPRB to fulfil its price review mandate. Therefore, rights holders and former rights holders are required to submit this information to the PMPRB within the timelines set out in the legislation. The information that must be submitted and related deadlines are set out in section 82 of the Act and in the Regulations. In 2022, two medicines were reported to the PMPRB for the first time despite being patented and sold prior to 2022 (see Table 2, Failure to Report the Sale of Patented Medicines).

FAILURE TO FILE PRICE AND SALES DATA (FORM 2)

Failure to file refers to the complete or partial failure of a rights holder to file the information required by the Act and the Regulations to the PMPRB. There were no Board Orders issued for failure to file in 2022.

TABLE 2. FAILURE TO REPORT THE SALE OF PATENTED MEDICINES

Rights holder	Trade name*	Medicinal ingredient	Year medicine reported to the PMPRB as under PMPRB jurisdiction	Year medicine reported to the PMPRB with subsequent patent
Sanofi-Aventis Canada Inc.	Trurapi (2 DINs)	Insulin aspart	2021	–
Sanofi-Aventis Canada Inc.	Admelog (2 DINs)	Insulin lispro	2019	–

* Drug Identification Numbers (DINs)
Data source: PMPRB

SCIENTIFIC REVIEW

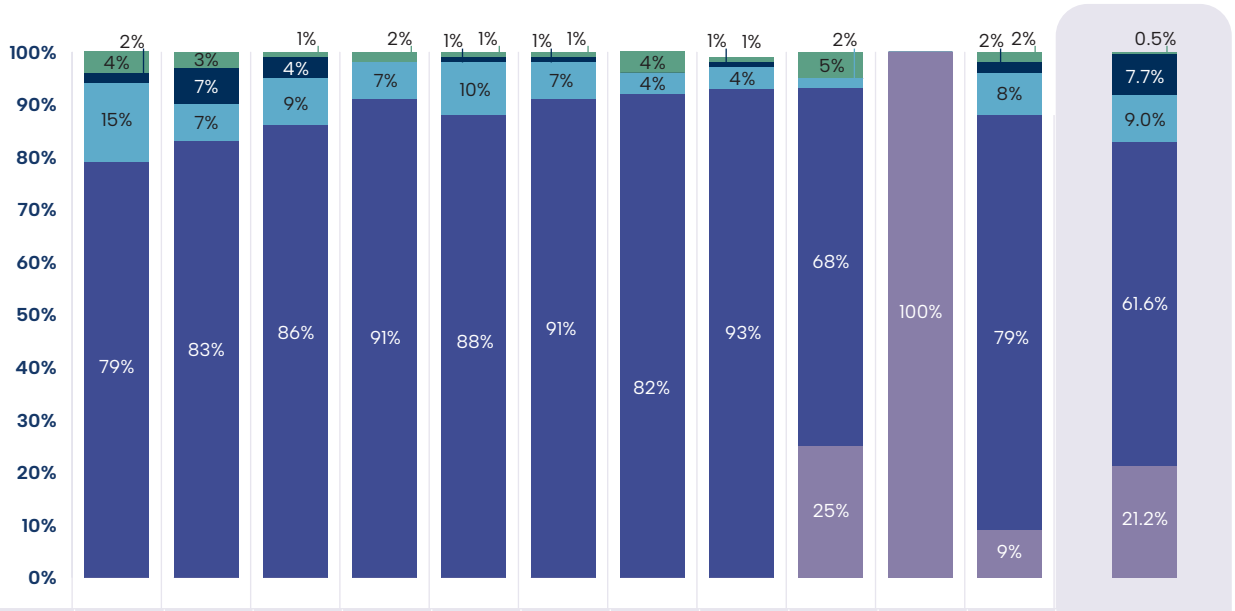
HUMAN DRUG ADVISORY PANEL

Under the Guidelines, which were operational until July 1, 2022, a scientific evaluation was done on all new patented medicines as part of the price review process. The PMPRB established the Human Drug Advisory Panel (HDAP) to provide recommendations on the categorization of patented medicines to Staff. The HDAP conducted an evaluation to provide clinical context pertaining to the scientific information that was being considered by Staff. HDAP members reviewed and evaluated the appropriate scientific information available, including any submission by a rights holder about the proposed level of therapeutic improvement, the selection of comparator medicines, and comparable dosage regimens.

The HDAP provided recommendations on the therapeutic benefit of new patented medicines according to the following definitions:

- **Breakthrough:** A medicine that is the first one sold in Canada to effectively treat a particular illness or effectively address a particular indication.
- **Substantial Improvement:** A medicine that, relative to other medicines sold in Canada, provides substantial improvement in therapeutic effects.
- **Moderate Improvement:** A medicine that, relative to other medicines sold in Canada, provides moderate improvement in therapeutic effects.
- **Slight or No Improvement:** A medicine that, relative to other medicines sold in Canada, provides slight or no improvement in therapeutic effects.

FIGURE 1. PERCENTAGE AND NUMBER OF NEW PATENTED MEDICINES REVIEWED, BY THERAPEUTIC BENEFIT



Number of New Patented Medicines Reviewed	2013 Intro	2014 Intro	2015 Intro	2016 Intro	2017 Intro	2018 Intro	2019 Intro	2020 Intro	2021 Intro*	2022 Intro†	Overall 2013–2022	Overall 2013–2022 Revenue Share
Under Review‡	–	–	–	–	–	–	–	–	15	69	84	21.2%
Slight/No Improvement	91	86	73	116	70	98	62	71	40	–	707	61.6%
Moderate Improvement	17	7	8	9	8	8	11	3	1	–	72	9.0%
Substantial Improvement	2	7	3	–	1	1	–	1	–	–	15	7.7%
Breakthrough	5	3	1	3	1	1	3	1	3	–	21	0.5%

* Updated to include reviews occurring after the previous Annual Report's reporting date of March 31, 2022

† Assessment as of March 31, 2023

‡ Due to the Amending Regulations and update of comparator countries, new medicine reviews were not conducted until such time as new Guidelines were finalized. As per the **Interim Guidance**, the status of a category of medicines including all new medicines is "under review".
Data source: PMPRB

Figure 1 shows the distribution of new patented medicines introduced from 2013 to 2022 by their level of therapeutic benefit. The largest percentage of patented medicines (78.6%) introduced since 2013 were categorized as "Slight or No Improvement" in therapeutic benefit over existing therapies.[4]

The "Overall 2013–2022" bar represents the therapeutic benefit breakdown for all new patented medicines introduced from 2013 to 2022. The "Overall 2013–2022 Revenue Share" bar illustrates the revenue share by therapeutic benefit for all new patented medicines introduced from 2013 to 2022.

As per the Interim Guidance issued by the Board on August 18, 2022, patented medicines without a maximum average potential price or non-excessive average price as of July 1, 2022, were not subject to price reviews by PMPRB Staff and are reported as "under review".

PRICE REVIEW

The PMPRB reviews the average price (net of reported discounts and deductions) and the list price of each strength of each individual dosage form of each patented medicine. In most cases, this unit is consistent with the Drug Identification Number(s) (DINs) assigned by Health Canada at the time the medicine is approved for sale in Canada.

NEW PATENTED MEDICINES REPORTED TO THE PMPRB IN 2022

For the purpose of this report, a new patented medicine in 2022 is defined as any patented medicine or new dosage form or strength of a patented medicine first sold in Canada, or previously sold but first patented, between December 1, 2021, and December 1, 2022.

There were 69 new patented medicines for human use reported as sold in 2022. Some are one or more strengths of a new active substance and others are new presentations of existing medicines. Of these 69 new patented medicines, six (8.7%) were sold in Canada prior to the issuance of the Canadian patent that brought it under the PMPRB's jurisdiction. Table 3 shows the year of first sale for these medicines.

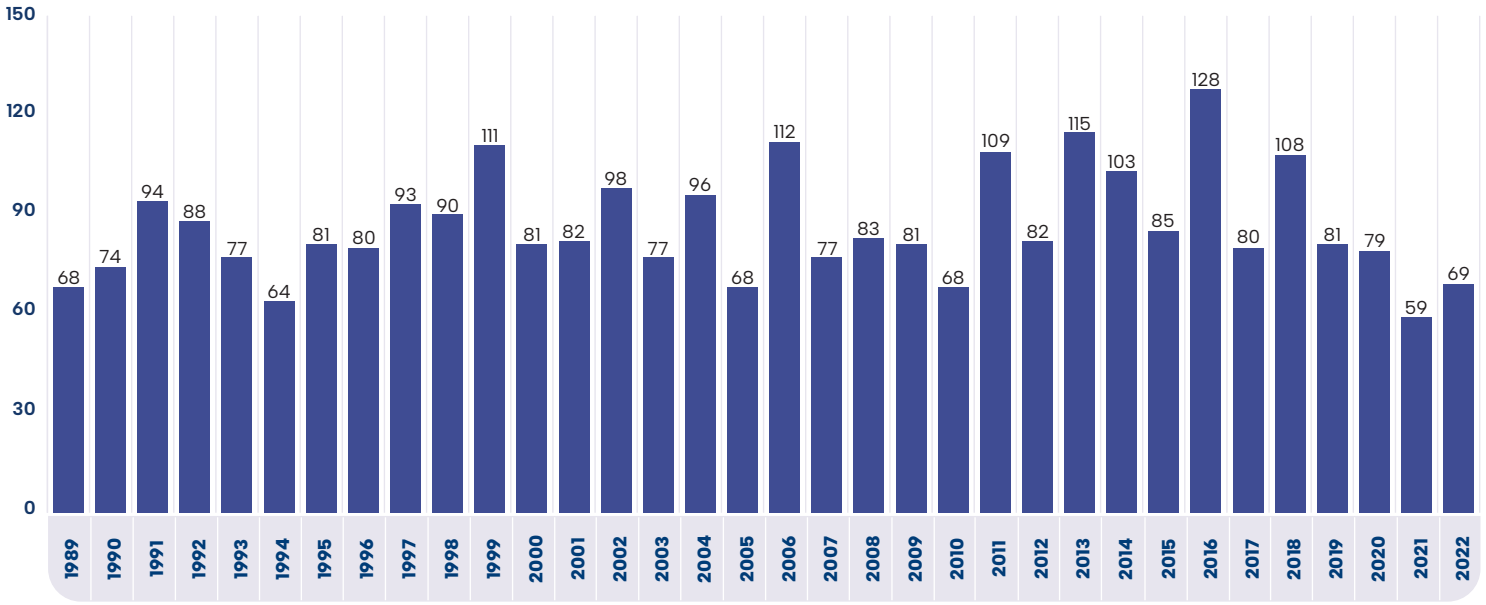
TABLE 3. NUMBER OF NEW PATENTED MEDICINES FOR HUMAN USE IN 2022 BY YEAR FIRST SOLD

Year first sold	Number of medicines
2020	1
2021	4
2022	1
Total	**6**

Data source: PMPRB

Figure 2 illustrates the number of new patented medicines for human use reported to the PMPRB from 1989 to 2022.

FIGURE 2. NUMBER OF NEW PATENTED MEDICINES FOR HUMAN USE



Data source: PMPRB

PRICE REVIEW OF EXISTING PATENTED MEDICINES FOR HUMAN USE IN 2022

For the purpose of this report, existing patented medicines include all patented medicines first sold and reported to the PMPRB prior to December 1, 2021.

At the time of this report, there were 1,069 existing patented medicines:

- 819 were not the subject of investigations;
- 197 were the subject of investigations;
- 36 were under review;
- 14 were the subject of a Voluntary Compliance Undertaking;
- 2 were subject to Board Order; and
- 1 was subject to a Settlement Agreement and Order.

Table 4 provides a summary of the status of the price review of the new and existing patented medicines for human use in 2022.

TABLE 4. PATENTED MEDICINES FOR HUMAN USE SOLD IN 2022—STATUS OF PRICE REVIEW AS OF MARCH 31, 2023

	New medicines introduced in 2022	Existing medicines	Total
Total	**69**	**1,069**	**1,138**
Not Subject to Investigation	0	819	819
Under Review	69	36	105
Subject to Investigation	0	197	197
Subject to Voluntary Compliance Undertaking (VCU)	0	14	14*
Subject to Board Order	0	2	2
Subject to Settlement Agreement and Order	0	1	1

* The terms and conditions of previous years' VCUs that have carried over into 2022 are captured in this count.
Data source: PMPRB

UPDATE FROM THE 2021 ANNUAL REPORT

- 22 of the patented medicines for human use that were reported as under review in the 2021 Annual Report remain under review.
- 56 of the 169 investigations reported in the 2021 Annual Report resulted in one of the following:
  - the closure of the investigation;
  - a VCU by the rights holder to reduce the price and offset potential excess revenues through a payment and/or a reduction in the price of another patented medicine (see "Voluntary Compliance Undertakings"); or
  - a public hearing to determine whether the price was excessive, including any remedial Order determined by the Board (see "Hearings").

PATENTED OVER-THE-COUNTER MEDICINES, PATENTED GENERIC MEDICINES, AND PATENTED MEDICINES FOR VETERINARY USE

The reduced reporting obligations for medicines with lowest risk of excessive pricing (i.e., veterinary, over-the-counter, and certain "generic" medicines) came into force on July 1, 2022, as provided for in the Amending Regulations. Staff only review the prices of patented over-the counter medicines, patented generic medicines, and patented veterinary medicines when a complaint of excessive pricing has been received. No complaint-based investigation was undertaken in 2022.

CERTIFICATES OF SUPPLEMENTAL PROTECTION

Amendments made to the Patented Medicines section of the Act, published in the **Canada Gazette**, which came into force on June 30, 2021, extended the PMPRB's jurisdiction to medicines that are protected by a Certificate of Supplementary Protection (CSP). A CSP gives the certificate holder the same legal rights given by the patent and extends patent protection for a maximum period of two years. There were 58 CSPs reported to the PMPRB in 2022, with expiration dates ranging from 2024 to 2037. Each patent that had their duration extended through a CSP can be linked to multiple patented medicines; in total, there are 144 patented medicines linked to these 58 CSPs.

VOLUNTARY COMPLIANCE UNDERTAKINGS AND HEARINGS

VOLUNTARY COMPLIANCE UNDERTAKINGS

A VCU is a promise by a rights holder to reduce its price(s) and/or offset any potential excess revenues from the sale of a patented medicine that is subject to an investigation. The consideration of a VCU is an administrative procedure and does not constitute an admission or determination by the PMPRB that the price submitted by the rights holder, or used to calculate a revenue offset, is not excessive. However, the acceptance of a VCU by the Chairperson will result in the closure of an investigation.

In 2022, the Chairperson approved the closure of investigations based on the receipt of eight VCUs. In addition to price reductions for certain medicines, potential excess revenues totaling $921,189.80 were offset by way of a payment to the Government of Canada.

No additional VCUs met the criteria for inclusion as of May 31, 2023.

TABLE 5. VOLUNTARY COMPLIANCE UNDERTAKINGS IN 2022 UP TO MAY 31, 2023

Patented medicine (Trade name)*	Therapeutic use	Rights holder	Date of approval	Offset of potential excessive revenues	
				Price reduction	Payment to the government
VCUs in 2022					
Gilteritinib (sold under trade name Xospata) (1 DIN)	Indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation.	Astellas Pharma Canada, Inc.	February	–	$400,000.00
Fremanezumab (sold under trade name Ajovy) (2 DINs)	Indicated for the prevention of migraine in adults who have at least four migraine days per month.	Teva Canada Innovation	February	Yes	–
Burosumab (sold under trade name Crysvita) (3 DINs)	Indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older; also indicated for the treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with tumors that cannot be curatively resected or localized in adult patients.	Ultragenyx Pharmaceuticals Inc.	February	Yes	–
Dalbavancin (sold under trade name Xydalba) (1 DIN)	Indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by gram-positive microorganisms.	Paladin Labs Inc.	April	Yes	$20,181.32
Halobetasol proprionate / tazarotene (sold under trade name Duobrii) (1 DIN)	Indicated for improving the signs and symptoms of plaque psoriasis in adult patients with moderate to severe plaque psoriasis.	Bausch Health, Canada Inc.	May	–	$107,814.48
Clevidipine (sold under trade name Cleviprex) (1 DIN)	Indicated for the management of acute elevation of blood pressure in perioperative settings.	Chiesi USA, Inc.	May	Yes	–
Chlormethine hydrochloride (sold under trade name Ledaga) (1 DIN)	Indicated for the topical treatment of stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) in adult patients who have received prior skin-directed therapy.	Recordati Rare Diseases Canada Inc.	May	–	–

Continued on next page...

Patented medicine (Trade name)*	Therapeutic use	Rights holder	Date of approval	Offset of potential excessive revenues	
				Price reduction	Payment to the government
VCUs in 2022					
Olopatadine hydrochloride (sold under trade name Patanol) and olopatadine hydrochloride (sold under trade name Pataday) (2 DINs)	Indicated for the treatment of allergic conjunctivitis and the treatment of ocular itching associated with seasonal allergic conjunctivitis, respectively.	Novartis Pharmaceuticals Canada Inc.	August	–	$393,194.00
Total for VCUs approved as of December 31, 2022					**$921,189.80**
VCUs in 2023 as of May 31, 2023					
–	–	–	–	–	–
Total for VCUs approved as of May 31, 2023					**$921,189.80**

* Drug Identification Number (DIN)

HEARINGS

The PMPRB holds hearings into two types of matters:

- excessive pricing; and
- failure to file–jurisdiction.

EXCESSIVE PRICING

When an investigation into the price of a patented medicine is completed, and the matter is not resolved, the Executive Director may submit a report to the Chairperson. The Chairperson may decide to issue a Notice of Hearing if he or she is of the opinion that it is in the public interest. During a hearing, submissions and evidence from the parties are heard by a Hearing Panel consisting of at least two Board members. The Hearing Panel determines whether a patented medicine is being, or has been, sold at an excessive price in any market in Canada by taking into consideration the available information relating to the factors set out in section 85 of the Act. If the Hearing Panel finds the price is excessive, it can issue an order to reduce the maximum price of the patented medicine in question (or of another patented medicine of the rights holder) and/or to offset revenues received as a result of the excessive price. Judicial review of Board decisions can be sought in the Federal Court of Canada.

In January 2019, the PMPRB announced it would hold a public hearing in the matter of the price of the patented medicine cysteamine bitartrate sold under the trade name Procysbi by Horizon Therapeutics Canada. The purpose of this hearing was to determine whether the medicine has been, or is being, sold in any market in Canada at a price that, in the Board's opinion, is or was excessive: and, if so, what order, if any, should be made to remedy the excessive pricing.

The hearing was held over several weeks in late 2020–early 2021, and in September 2022, a decision was issued by the Hearing Panel that found that the price of Procysbi was excessive under section 83 and 85 of the *Patent Act*. On October 13, 2022, the Board ordered Horizon to pay $22,028,977.26 to the Receiver General of Canada within 30 days of the order date. This was coupled with an order that the ceiling price of Procysbi be reduced to a non-excessive level.

FAILURE TO FILE–JURISDICTION

When it appears that a rights holder has failed or refused to provide the PMPRB with the pricing, sales, or revenues and like information required by law, the Executive Director may submit a report to the Chairperson. The Chairperson may decide to issue a Notice of Hearing if he or she is of the opinion that it is in the public interest to hold a hearing to determine whether the rights holder has, in fact, breached the reporting requirements of the Act and Regulations. If the Hearing Panel finds, as the result of a public hearing, that the rights holder has failed to report the required information, the Hearing Panel can order the rights holder to file the required pricing and sales information.

There were no new failure to file hearings as of March 31, 2023.

On May 7, 2020, the Board issued its decision on redetermination on its decision dated December 19, 2016, whereby the Board originally found that Canadian Patent No. 2,478,237 pertains to the patented medicine adapalene sold under the trade name Differin and ordered Galderma to file the required information for the period between January 1, 2010, and March 14, 2016. The Board's decision on redetermination again ordered Galderma to file the required information for the period between January 1, 2010, and March 14, 2016. On August 11, 2020, Galderma Canada Inc. filed an application for judicial review of the Board's May 7, 2020, decision on redetermination (T-906-20), which is still pending.

SUMMARY

Excess revenues and potential excess revenues totaling $31,278,774.47 were offset by payments to the Government of Canada through VCUs, settlements, and Board Orders in 2022 and up to May 31, 2023.

Since 1993, 170 VCUs have led to investigation closures. In addition, 31 notices of hearing have been issued, 14 of which were resolved through settlements prior to the hearing on the merits and 17 of which were subject to a full public hearing on the merits (10 related to allegations of excessive pricing and 7 related to allegations of failure to file). These measures resulted in price reductions and the offset of excess revenues or potential excess revenues by additional price reductions and/or payments to the Government of Canada. Over $241 million has been collected through VCUs, settlements, and Board Orders through payments to the Government of Canada.

MATTERS BEFORE THE FEDERAL COURT, FEDERAL COURT OF APPEAL, AND SUPREME COURT OF CANADA OR OTHER COURTS

A-237-19: on October 20, 2017, Alexion Pharmaceuticals Inc. filed an application for judicial review of the Board's decision dated September 20, 2017, in respect of its finding that the patented medicine eculizumab sold under the trade name Soliris was being sold at an excessive price in Canada and ordering Alexion to lower its price (currently stayed) and make an excess revenue payment of $4,245,329.60. The Board's decision was found to be reasonable by the Federal Court via a decision dated May 23, 2019. Alexion has appealed the Federal Court's decision in the Federal Court of Appeal. The Federal Court of Appeal heard the appeal of the Board Panel's decision in October 2020. The Federal Court of Appeal granted Alexion's appeal on July 29, 2021, and remitted the matter to the Board for redetermination. On June 21, 2022, the matter was settled through a Board order granting a discontinuation of the redetermination and related settlement agreement.

T-906-20: on January 18, 2017, Galderma Canada Inc. filed an application for judicial review of the Board's decision dated December 19, 2016. In that decision the Board found that Canadian Patent No. 2,478,237 pertains to the patented medicine adapalene sold under the trade name Differin and ordered Galderma to file the required information for the period between January 1, 2010, and March 14, 2016. The Federal Court granted Galderma's judicial review application on November 9, 2017, and quashed the Board's decision. On November 21, 2017, the Attorney General appealed the Federal Court's grant of the judicial review application. On June 28, 2019, the Federal Court of Appeal granted the appeal and issued its decision sending the matter back to the Board for redetermination. The Board's decision on redetermination, issued on May 7, 2020, again ordered Galderma to file the required information for the period between January 1, 2010, and March 14, 2016. On August 11, 2020, Galderma Canada Inc. filed an application for judicial review of the Board's May 7, 2020, decision on redetermination (T-906-20). The Board Panel's redetermination in this matter is under judicial review by the Federal Court.

T-1419-20: on November 23, 2020, Innovative Medicines Canada and 19 individual pharmaceutical companies brought an application in Federal Court for judicial review of the PMPRB's decision to issue new Guidelines on October 23, 2020 (then slated to come into effect in July 1, 2021). The application sought a declaration that the new Guidelines are *ultra vires* the *Patent Act* and an order quashing and setting aside the decision of the PMPRB to issue the new Guidelines. The matter was discontinued in August of 2022.

There are no PMPRB-related matters before the Supreme Court of Canada.

One judgment was rendered on a challenge related to PMPRB legislation that commenced in 2019:

T-1465-19: on September 6, 2019, Innovative Medicines Canada (IMC) and sixteen individual pharmaceutical companies brought an application in Federal Court to judicially review s. 4 (new factors), s. 6 and Schedule (new basket of countries), and ss. 3(4) (new net price calculation) of the 2019 Amendments to the *Patented Medicines Regulations* on the basis that they were *ultra vires* the regulation-making power contained in the *Patent Act*. The Federal Court issued its decision on June 29, 2020, and held that the amendments in s 4, s. 6 and the Schedule are *intra vires* the *Patent Act*, but that the amendment in ss. 3(4) is not. On September 10, 2020, IMC and the individual pharmaceutical companies filed a Notice of Appeal (A-215-20) with respect to the Federal Court decision. The Attorney General of Canada also filed a cross-appeal in respect of the invalidated amendments. Judgement on the matter was rendered on December 5, 2022, with the FCA dismissing the appellant's challenge on the change of the list of comparator countries, and not rendering a decision on additional issues which had been rendered moot.

No. 500-17-109270-192. Merck et al. v Canada (Attorney General): on August 22, 2019, six individual pharmaceutical companies brought an application for judicial review in Quebec Superior Court challenging the constitutionality of ss. 79-103 of the *Patent Act*. In its decision issued on December 18, 2020, the Quebec Superior Court found the amendments to subsections 4(4)a) and 4(4)b) that would update the net price calculation to require patentees to include discounts and rebates provided to third parties unconstitutional and of no force or effect. The Court found the rest of the Regulations, including the other amendments, and the relevant sections of the *Patent Act* constitutionally valid. The pharmaceutical company applicants filed a Notice of Appeal with respect to the Superior Court of Quebec's decision on January 25, 2021, and the Attorney General of Canada also filed a cross-appeal in respect of the invalidated amendments. The Quebec Court of Appeal granted the appeal in part and dismissed the cross-appeal on February 18, 2022.

TABLE 6. STATUS OF BOARD PROCEEDINGS IN 2022 UP TO MAY 31, 2023

Allegations of Excessive Pricing				
Medicine	**Indication/use**	**Rights holder**	**Issuance of notice of hearing**	**Status**
Eculizumab (sold under trade name Soliris)	Paroxysmal nocturnal hemoglobinuria Atypical hemolytic uremic syndrome	Alexion Pharmaceuticals Inc.	January 20, 2015	Board Order: September 27, 2017 Found the price of Soliris was and is excessive under Sections 83 & 85 of the Act. Payment of excess revenues: $4,245,329.60 * Application for Judicial Review and subsequent appeal: see below. Matter (redetermination) discontinued on June 21, 2022, following a settlement agreement.
Cysteamine bitartrate (sold under trade name Procysbi)	Nephropathic cystinosis	Horizon Therapeutics Canada	January 14, 2019	Hearing held in 2020–2021. Decision issued September 1, 2022, found the price of Procysbi was excessive under Sections 83 and 85 of the Act. Board order: October 13, 2022 Payment of excess revenues: $22,028,977.26 Ceiling price of Procysbi to be reduced to a non-excessive level.

Allegation of Failure to File				
Medicine	**Indication/use**	**Rights holder**	**Issuance of notice of hearing**	**Status**
Adapalene (sold under trade names Differin and Differin XP)	Acne	Galderma Canada Inc.	(redetermination)	Board Order: May 7, 2020. Galderma to file the required information for the requested period. * Application for Judicial Review and prior litigation: see below.

Judicial Review of Board Decisions and Appeals pending as of May 31, 2023				
Medicine	**Indication/use**	**Applicant**	**Issue**	**Date of notice of hearing/status**
Adapalene (sold under trade names Differin and Differin XP)	Acne	Galderma Canada Inc.	Failure to file (jurisdiction)	Application for Judicial Review. Court File T-83-17 (Re. Board Panel's decision of December 19, 2016): Decision issued November 9, 2017, quashing in part Board Panel's decision. Notice of Appeal (Federal Court of Appeal) filed on November 21, 2017. Court File A-385-17. Decision issued on June 28, 2019. Matter sent for redetermination by the Board. Redetermination decision issued on May 7, 2020. Application for Judicial Review. Court File T-906-20 (Re. Board Panel's Decision of May 7, 2020) filed on August 11, 2020. Matter pending.
N/A	N/A	Innovative Medicines Canada et al	*Vires* of new Guidelines issued by the PMPRB in October 2020	Application for Judicial Review. Court File T-1419-20: discontinued in August of 2022.

ENDNOTES

[1] 4.1% growth in drug spending is the average growth rate in drug spending as calculated from the Canadian Institute for Health Information (CIHI), National Health Expenditure Trends, 1975 to 2022 Series C data.

[2] CIHI, National Health Expenditure Trends, 2022

[3] Statistics Canada, Insights on Canadian Society: Pharmaceutical access and use during the pandemic (November 2022)

[4] The criteria for commencing an investigation have been developed with the intention of making the most efficient use of the PMPRB's human and financial resources. The fact that the price of a patented medicine is not subject to an investigation does not necessarily mean that its price is not excessive and vice versa. It only means that the investigation criteria under the Guidelines have not been met in the particular circumstances.

381 PUBLIC

KEY PHARMACEUTICAL TRENDS:

HIGHER-COST MEDICINES CONTINUE TO INFLUENCE SALES

Pharmaceutical spending is influenced by many factors, including price, utilization, the entry of newer, higher-cost medicines, and the loss of market exclusivity for older patented medicines. In 2022, there was a sizable increase in the volume of patented medicines sold, as well as a moderate rise in the sales of higher-cost medicines, resulting in an overall increase in total spending of 5.7%. Canadian list prices of patented medicines remained among the highest in the Organisation for Economic Co-operation and Development (OECD), ranking second, behind only the US.

The PMPRB is responsible for reporting on trends in pharmaceutical sales and pricing for all medicines, patented and non-patented, and for reporting research and development spending by rights holders.

Under the Regulations, rights holders are required to submit detailed information on their sales of patented medicines, including quantities sold, gross ("list") and net prices, and net revenues. The PMPRB uses this information to analyze trends in the sales, prices,[5] and use of patented medicines.[6] This section provides key trends, including analyses of Canadian national, public, and private payer markets for all medicines. Note that any reference to sales in this section should be interpreted as sales revenues unless otherwise noted.

DISCLAIMERS

1. Although select statistics reported in the KEY PHARMACEUTICAL TRENDS section are based in part on data obtained under license from the MIDAS® database and the Private Pay Direct Drug Plan database proprietary to IQVIA Solutions Canada Inc. and/or its affiliates ("IQVIA"), the statements, findings, conclusions, views, and opinions expressed in this Annual Report are exclusively those of the PMPRB and are not attributable to IQVIA.
2. To provide a broader perspective on pharmaceutical trends in Canada, summaries of the results of National Prescription Drug Utilization Information System (NPDUIS) analyses have been included as additional "Brief Insights" throughout this section. A variety of public and licensed data sources are used for NPDUIS analytical studies. Many of these sources do not differentiate between patented and non-patented generic medicines; in these instances, the general term "generic" is used to include both. NPDUIS is a research initiative that operates independently of the price review activities of the PMPRB. Analysis produced under the NPDUIS initiative does not contain information that is confidential or privileged under sections 87 and 88 of the *Patent Act*.

$6.7 BILLION

of Canadian pharmaceutical sales in 2022 were for medicines that previously but no longer report to the PMPRB.

TRENDS IN SALES OF PATENTED MEDICINES

Canadians spend much more on patented medicines today than they did a decade ago. Over the last five years, sales of these medicines have grown by an average of 1.8% per year, reaching $18.4 billion in 2022. This section looks at the most important factors driving the change in sales revenues from 2021 to 2022 and compares them to trends from previous years.

TRENDS IN SALES REVENUES

Figure 3 reports on trends in the sales of patented medicines from 1990 to 2022. Between 2021 and 2022, there was a $956 million (5.7%) increase in the sales of patented medicines. While there has been more than a ten-fold increase in annual sales since 1990, the year-over-year rate of change within that period has varied. This trend is highlighted by the five-year compound annual growth rate given in Figure 3(b), which has ranged between -1.7% and 9.4% since 2013.

Figure 3(a) gives the sales of patented medicines as a share of overall medicine sales. This share reached a peak of 72.7% in 2003 before declining to 60.7% in 2013. In 2022, patented medicines accounted for 49.0% of the sales of all medicines in Canada.

The trends in sales per capita and sales as a percentage of the gross domestic product (GDP) displayed in Figure 3(c) show the ongoing importance of patented medicines in the Canadian economy. Overall, per capita sales of patented medicines rose from $61.60 in 1990 to $465.12 in 2022, while sales as a percentage of GDP rose from 0.25% in 1990 to 0.67% in 2022.

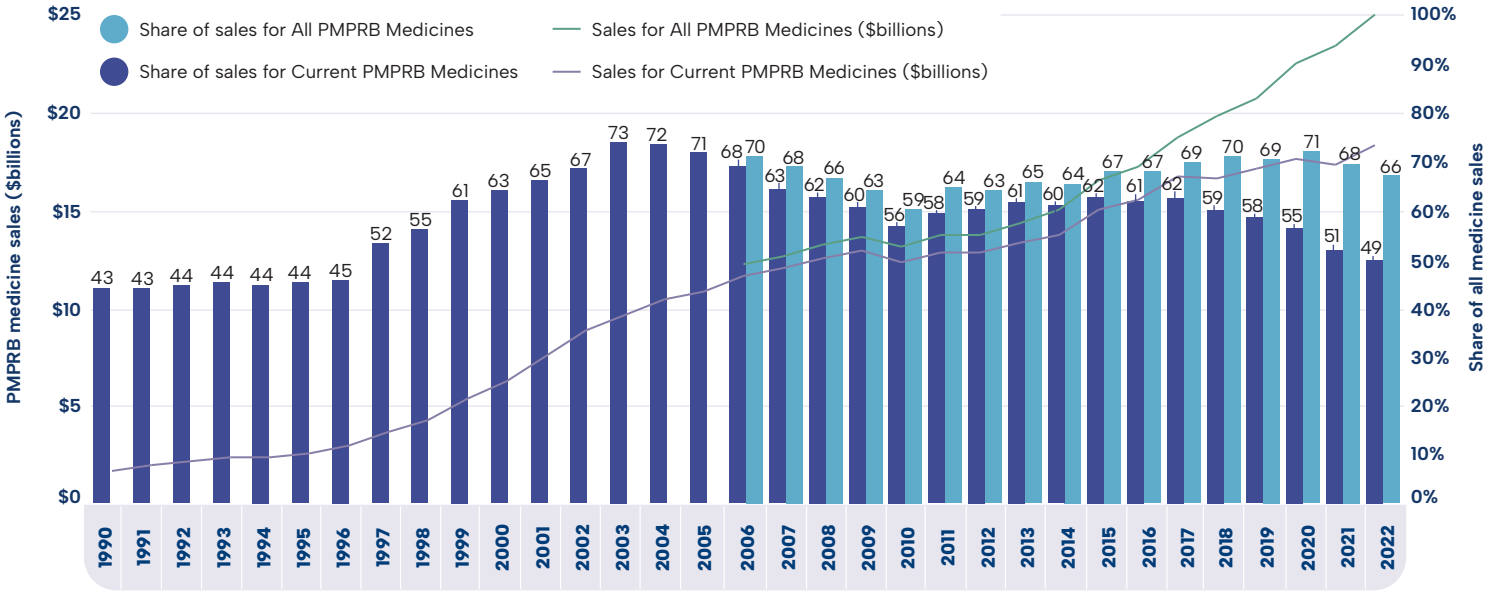
To highlight the continuing impact of patented medicines, Figures 3(a) and 3(b) also provide results for "All PMPRB Medicines". This broader category includes all medicines, current and historic, that ever reported sales to the PMPRB. Historically, medicines have experienced a substantial decrease in market share upon loss of patent protection; however, that same effect has not been observed in a number of the medicines that have stopped reporting to the PMPRB in recent years.

Sales for All PMPRB Medicines rose by 6.8% in 2022, reaching $25.1 billion or 66% of the sales of all medicines in Canada. Medicines that previously reported to the PMPRB accounted for estimated sales of $6.7 billion, or 26.6% of All PMPRB Medicine sales. This is considerably more than a decade ago when medicines that formerly reported to the PMPRB accounted for $1.0 billion, or 6.9% of All PMPRB Medicine sales.

A complete table of the data presented in Figure 3 for patented medicines currently reporting to the PMPRB is included in Appendix 2.

FIGURE 3. TRENDS IN PATENTED MEDICINE SALES, 1990 TO 2022

(a) Patented medicine share of all medicine sales: Current PMPRB Medicines and All PMPRB Medicines*

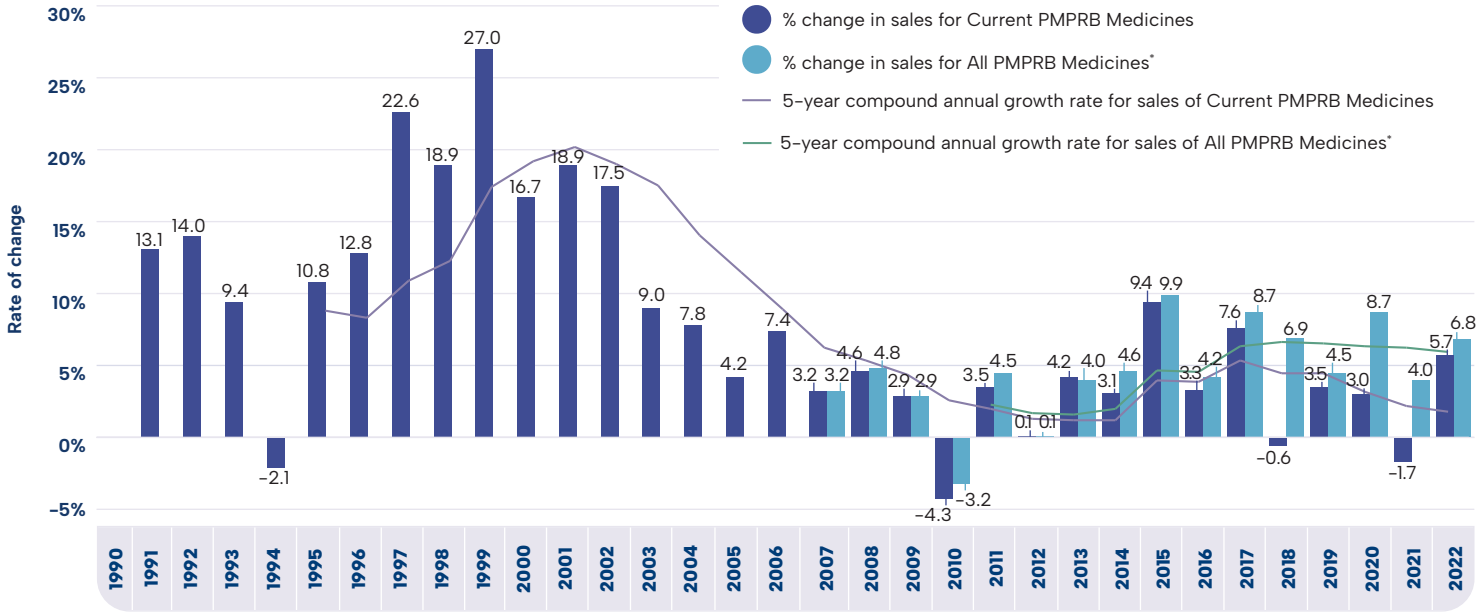


Note: To account for revised submissions from rights holders, sales are recalculated for the five years preceding the current Annual Report year. If the data has been revised, the values reported here may differ from those presented in earlier Annual Reports.

* Includes sales of currently patented medicines and medicines that once reported to the PMPRB but are no longer reporting a patent.

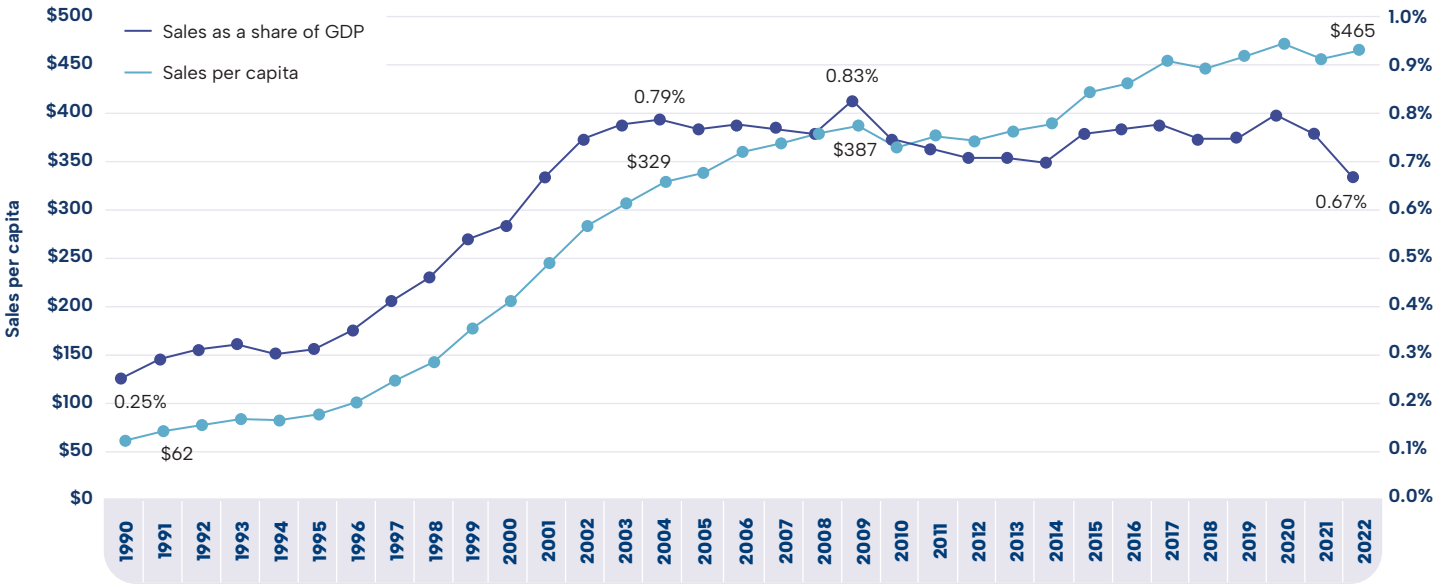
Data source: PMPRB; MIDAS® database, 1990–2022, IQVIA (all rights reserved)

(b) Rate of change in patented medicine sales: Current PMPRB Medicines and All PMPRB Medicines*



Note: As data is updated each year, historical results may not exactly match those reported in previous editions.
* Includes sales of currently patented medicines and medicines that once reported to the PMPRB but are no longer reporting a patent.
Data source: PMPRB; MIDAS® database, 1990–2022, IQVIA (all rights reserved)

(c) Patented medicine sales per capita and as a share of GDP: Current PMPRB Medicines



Data source: PMPRB; Statistics Canada; OECD

BRIEF INSIGHTS:

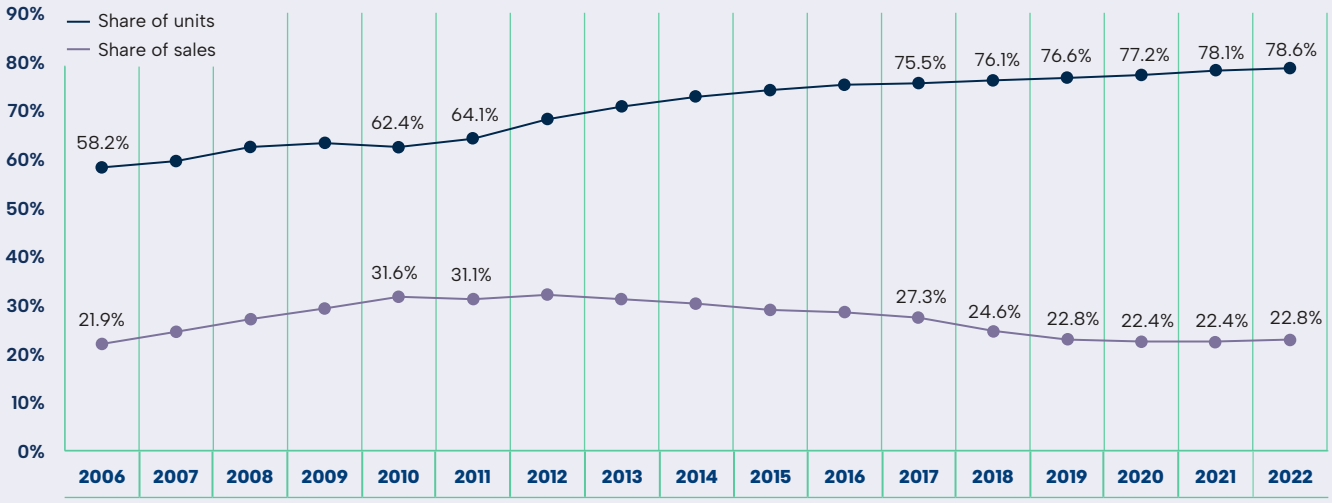
TRENDS IN THE SALES OF GENERIC MEDICINES

While sales of patented medicines increased by 5.7% in 2022, retail sales of generic medicines rose by 10.6%, from $5.88 billion in 2021 to $6.50 billion in 2022. This is a notable increase over the generally low or negative rates of change observed since 2010, which were due in large part to the introduction of price-setting policies initiated by individual provincial governments and through the pan-Canadian Pharmaceutical Alliance (pCPA).

In 2018, the introduction of a five-year joint agreement between the pCPA and the Canadian Generic Pharmaceutical Association (CGPA) reduced the prices of 67 generic medicines to 10% or 18% of their reference brand price, driving expenditures down to virtually the same level as in 2010, even as generics continued to grow as a share of units sold in the retail pharmaceutical market (Figure 4).

As the prices of generic medicines begin to stabilize, the return to higher rates of sales growth in 2022 reflects a sustained increase in the use of generics over the previous year.

FIGURE 4. GENERIC SHARE OF THE CANADIAN PHARMACEUTICAL RETAIL MARKET, 2006 TO 2022



Note: The results reflect prescription sales in the national retail market based on manufacturer ex-factory list prices.
Data source: MIDAS® database, 2006–2022, IQVIA (all rights reserved)
[NPDUIS Report: *Generics360, 2018* – graph updated to include data up to 2022]

DRIVERS OF THE GROWTH IN SALES REVENUES

The growth in the sales revenues of patented medicines is influenced by changes in several key factors:

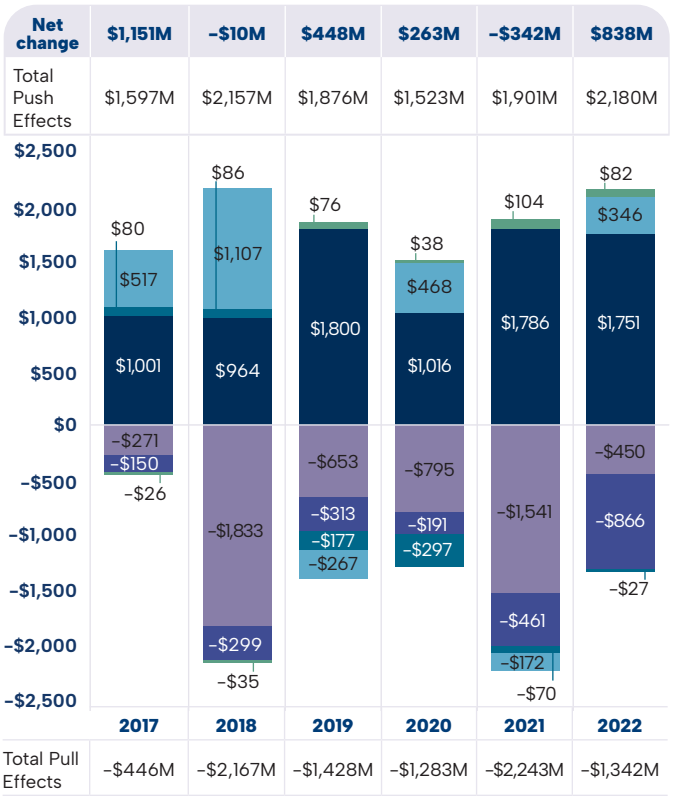
- **Volume effect:** changes in the quantity or amount of patented medicines sold.
  - This effect focuses on established medicines that were on the market for the period analyzed. Increases in the population, changes in demographic composition (e.g., shifts in the age distribution), increases in the incidence of disease, and changes in prescribing practices are among the factors that may contribute to this effect.
- **Mix effect:** shifts in use between lower- and higher-cost patented medicines.
  - This effect applies to both new medicines and those that were already on the market. The switch to new higher-priced medicines, the use of new medicines that treat conditions for which no effective treatment previously existed, and changes in prescribing practices are among the factors that may contribute to this change.
- **Exiting effect:** previously patented medicines that have stopped reporting sales revenues to the PMPRB or are no longer sold in Canada.
- **Loss-of-exclusivity effect:** medicines that have lost market exclusivity and are open to some level of generic competition but are still patented.
- **Price effect:** changes in the prices of existing patented medicines.
  - This effect applies to both increases and decreases in the prices of patented medicines over the time period analyzed.

Some factors, such as the mix effect, will generally put an upward pressure on sales, while others, such as the loss-of-exclusivity effect, have the opposite effect.

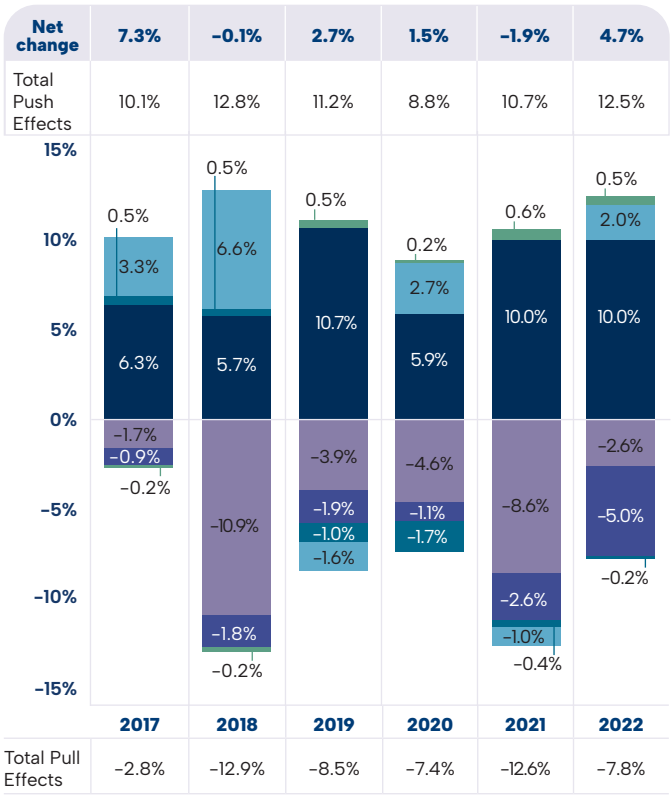
Figure 5 summarizes the major factors that drove the year-by-year change in patented medicine sales[7] between 2017 and 2022 (a) in absolute dollar amounts, and (b) as proportions of the overall annual change in sales.

FIGURE 5. KEY DRIVERS OF CHANGE IN THE SALES OF PATENTED MEDICINES, 2017 TO 2022

(a) Absolute change ($millions)



(b) Relative change (%)



Price | Volume | Mix, DAAs for Hepatitis C | Mix, Other Drugs | Loss-of-Exclusivity | Exiting

Note: When multiple factors change simultaneously, they create a residual or cross effect, which is not reported separately in this analysis, but is accounted for in the total cost change.

Values may not add to the net change due to rounding and the cross effect.

As this model uses various measures to isolate the factors contributing to growth, the net change reported here may differ slightly from the reported overall change in the patented medicines market reported in Figure 3(b).

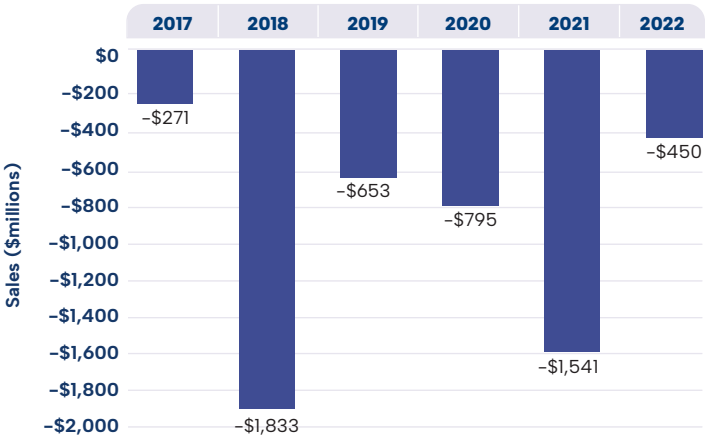
Data source: PMPRB

Changes in the prices of patented medicines have played a minor role in the growth in patented medicine sales over the last several years, suggesting that, on average, the prices of existing patented medicines are fairly stable. However, this does not reflect the overall increases in treatment costs due to the entry of newer, higher-priced patented medicines, the impact of which is captured by the mix effect.

The shift to new higher-cost patented medicines has been a major driver of sales growth in recent years. In 2022, the use of higher-cost patented medicines other than DAAs put an upward pressure on expenditures of $1.8 billion (push effect of 10.0%). While growth was observed in many therapeutic areas, the increase in sales of "antineoplastic and immunomodulating agents" exceeded that of any other class. These medicines, which include oncology treatments, accounted for more than 44% of all patented medicine sales in 2022. Results by therapeutic class are discussed in further detail in the upcoming sections.

Counterbalancing the upward sales pressure from the mix effect, there was a moderate market segment shift as some high-selling medicines stopped reporting their sales to the PMPRB. The loss-of-exclusivity effect accounted for a pull effect of $0.87 billion (-5.0%) on sales in 2022. Figure 6 illustrates the change in the impact of the exiting effect since 2017 and identifies the 10 top-selling medicines that stopped reporting to the PMPRB in 2022.

FIGURE 6. PULL EFFECT ON PATENTED MEDICINE SALES FROM THE EXITING EFFECT, 2017 TO 2022



Note: If a medicine stops reporting a patent mid-way through the year, its impact may be reflected in the exiting effect in more than one reporting year. The amounts reported in any given year may not reflect an entire year's worth of sales for these medicines.
Data source: PMPRB

Top-selling medicines that stopped reporting to the PMPRB in 2022	
Breo Ellipta	-$69M
Brilinta	-$47M
Myozyme	-$41M
Somatuline Autogel	-$36M
Prolia	-$23M
Vaxzevria	-$19M
Avamys	-$16M
Pentasa	-$15M
Pristiq	-$15M
Onglyza	-$15M

BRIEF INSIGHTS:

COST DRIVERS OF PUBLIC AND PRIVATE DRUG PLANS

Canadian public drug plans and private insurers together account for over three quarters of all prescribed drug spending in Canada.[i] This includes sales for all products reimbursed by the plan, including but not limited to patented and non-patented brand medicines, patented and non-patented generic medicines, and non-patented single-source medicines.

Drug costs, including markups, represent the largest component of prescription drug expenditures and have the greatest influence on overall trends. Drug costs rose by 8.4% in public plans in 2021/22 and 4.5% in private plans in 2022.

The increasing use of higher-cost medicines, or the drug-mix effect, is the primary cost driver for Canadian public and private drug plans. Over the past several years, higher-cost medicines (other than DAAs for hepatitis C) have exerted a consistent and significant upward pressure on expenditures, accounting for an 8.1% contribution toward drug costs in public plans in 2021-22 and 5.0% toward private plan costs in 2022. Given that the impact of DAA drugs on spending growth is dwindling, having had less than 0.1% pull effects in both public and private drug plans in the past year, the DAA effect is no longer separated out from the drug-mix effect.

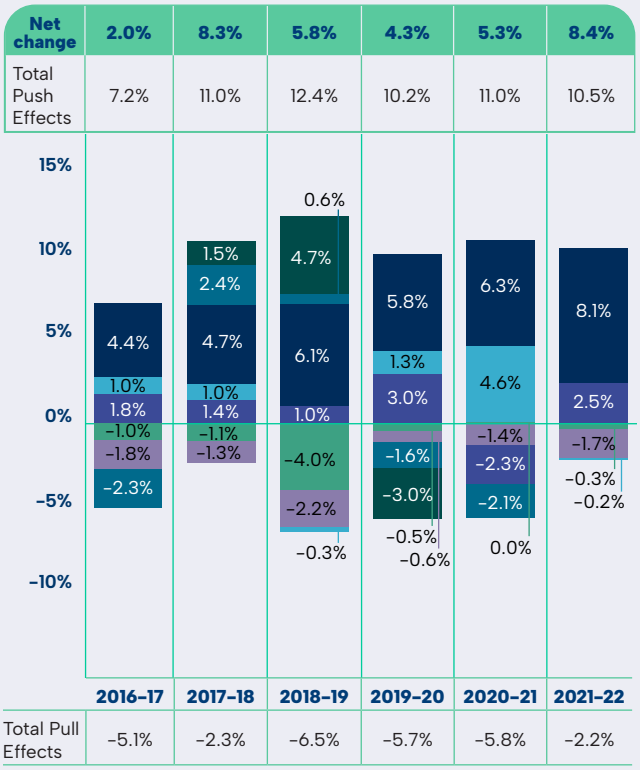
The significant downward force exerted by generic pricing policies implemented in 2018, captured under the price change effect, has stabilized and is no longer offsetting the increasing cost pressures from the drug-mix effect. The pull-down effect from substitution became stronger than price effect, lowering drug costs by 1.7% in public plans in 2021-22 and 2.0% of private plans in 2022. Additional savings are expected to be realized from the substitution effect in the coming years as a result of recent biosimilar policy changes in most public drug plans, as well as initiatives introduced by some private payers aimed at promoting switching from biologic originators to available biosimilars. As of March 2023, biosimilar substitution policies have been adopted by public plans in British Columbia, Alberta, Saskatchewan, Ontario, Quebec, New Brunswick, Nova Scotia, Newfoundland and Labrador, the Northwest Territories, and Yukon, and policies are under development for the remaining jurisdictions. With a strong market for biologics in Canada, these efforts may act as a means of offsetting the mounting pressure from higher-cost medicines.

For public plans, a 2.5% demographic push effect from the increased number of active beneficiaries in 2021-22 indicates the gradual returning of these drivers to pre-pandemic levels.

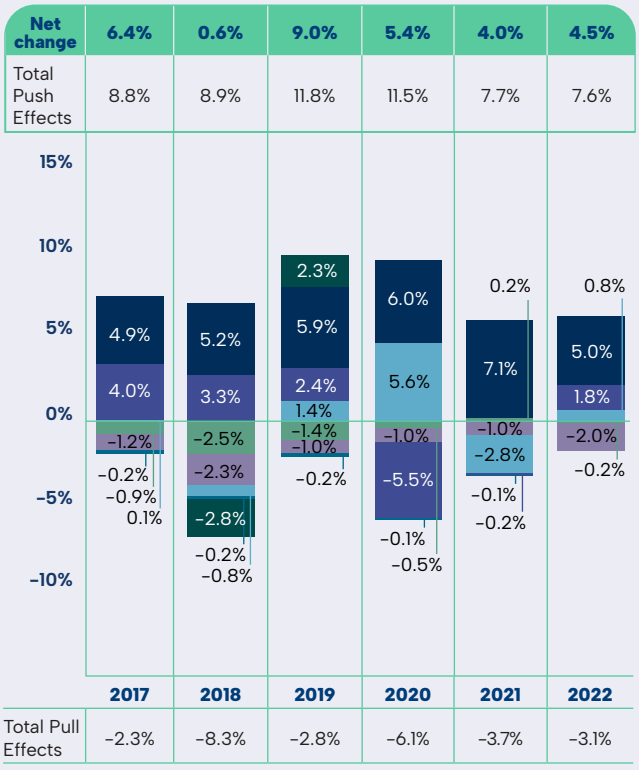
Continued on next page...

FIGURE 7. MEDICINE COST DRIVERS

(a) NPDUIS public drug plans*, 2016–17 to 2021–22



(b) Private drug plans, 2017 to 2022



OHIP+ | Drug-Mix, DAAs for Hepatitis C | Drug-Mix, Other Drugs | Volume† | Substitution | Price Change | Demographic†

Note: Public plans report on a fiscal year basis and private plans report on the calendar year. This has an impact on the magnitude of the effect of policies such as the OHIP+ program or the generic pricing initiative introduced in 2018, for which most of the impact on public plans was felt in the 2018–19 fiscal year.

When multiple factors change simultaneously, they create a residual or cross effect, which is not reported separately in this analysis, but is accounted for in the total cost change.

Values may not add to the net change due to rounding and the cross effect.

* British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon, and the Non-Insured Health Benefits (NIHB) Program. Results for 2020–21 onward do not include the NIHB program.

† A temporary partial data discontinuity from the private drug plans data supplier in 2021 and 2022 influenced the results for the demographic and volume effects. As such, the next Annual Report may include a revised estimate of these effects for those two years.

Data source: NPDUIS database, Canadian Institute for Health Information; IQVIA Private Pay Direct Drug Plan database

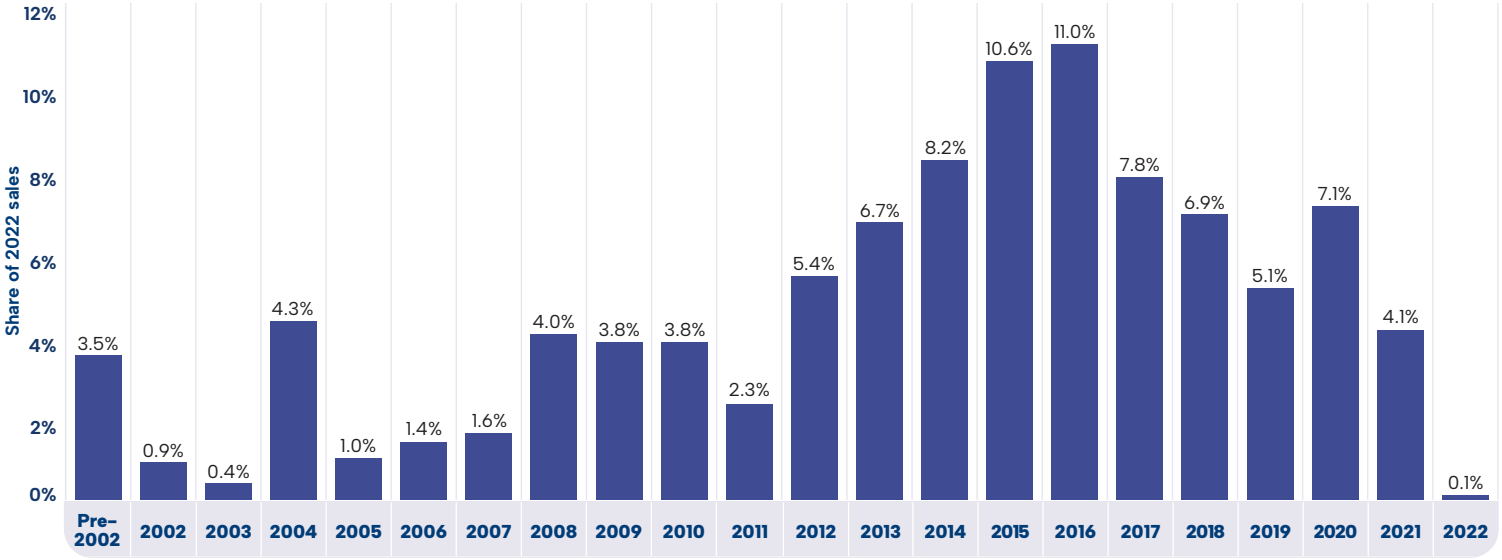
[i] Canadian Institute for Health Information. 2020. *Prescribed Drug Spending in Canada, 2020: A Focus on Public Drug Programs.* Ottawa, ON: CIHI. Available: https://www.cihi.ca/sites/default/files/document/prescribed-drug-spending-in-canada-2020-report-en.pdf

[NPDUIS Report: *CompassRx 2021/22*; NPDUIS Poster: Pressures behind the Rising Costs in Canadian Private Drug Plans, 2018 – graph updated to 2022]

NEWER MEDICINES DRIVING SALES REVENUES

Figure 8 breaks down the 2022 sales of patented medicines according to the year in which the medicine was first issued a Notice of Compliance (NOC) by Health Canada. Throughout the latter part of the 1990s and early 2000s, sales growth was largely driven by a succession of new "blockbuster" medicines that ultimately achieved very high sales volumes. As the patents for these medicines expired, their share of sales gradually decreased. In recent years, the introduction of new higher-cost medicines such as biologics, oncology medicines, and treatments for hepatitis C has accounted for a growing share of sales.

FIGURE 8. SHARE OF 2022 SALES OF PATENTED MEDICINES BY DATE OF FIRST NOTICE OF COMPLIANCE (NOC)



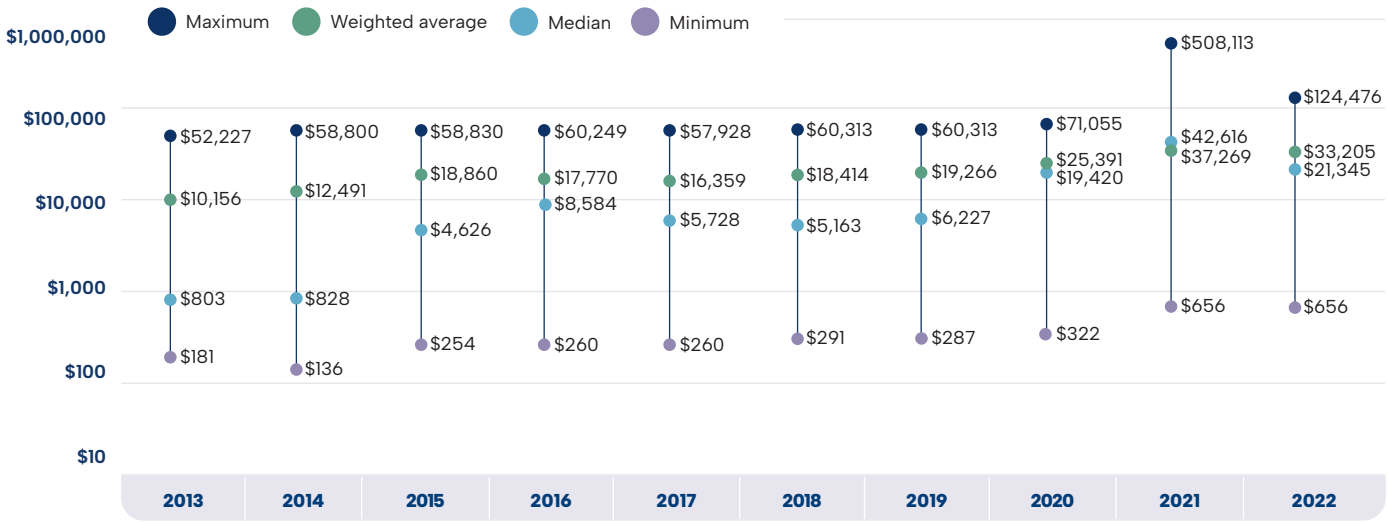
Data source: PMPRB

HIGHER-COST MEDICINES DRIVING SALES REVENUES

Over the last decade, there has been a notable shift in pharmaceutical development toward more specialized medicines, with an increasing number of higher-cost medicines entering the market and accounting for a substantial share of sales.

Figure 9 details the trend in the treatment costs of patented medicines since 2013. For many years, the majority of the 20 top-selling patented medicines had annual treatment costs under $1,000, but in recent years, costs for the top-sellers have soared into the thousands or tens of thousands of dollars. In 2022, the top 20 medicines, which accounted for 37.7% of patented medicine sales, had a median annual treatment cost of $21,345, more than 25 times the median in 2013.

FIGURE 9. ANNUAL TREATMENT COSTS FOR THE 20 TOP-SELLING PATENTED MEDICINES, 2013 TO 2022



Data source: PMPRB; IQVIA Private Pay Direct Drug Plan database, 2013–2022

High-cost medicines continue to dominate the pharmaceutical landscape

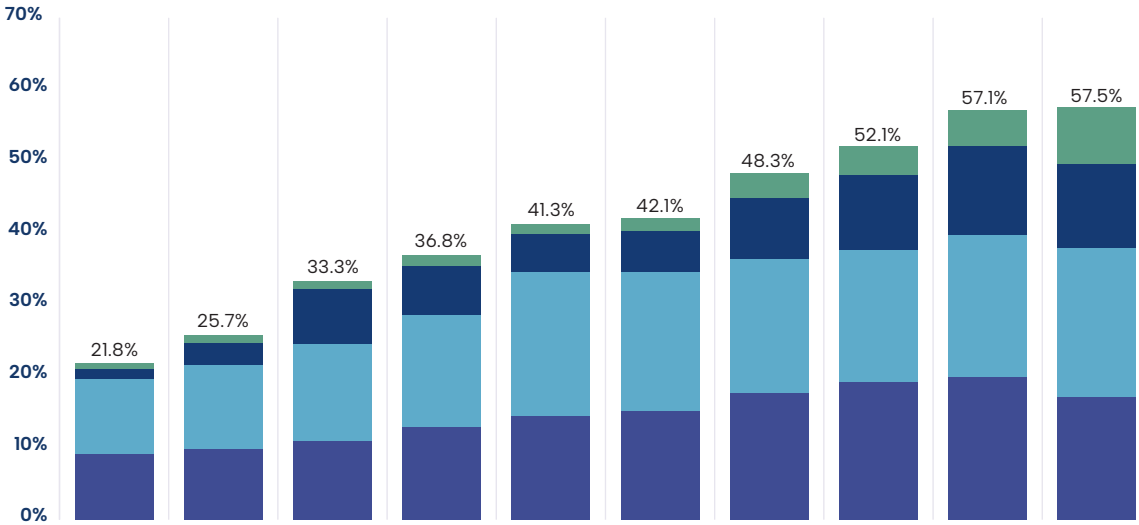
The 20 top-selling medicines in 2022 had a

MEDIAN ANNUAL TREATMENT COST OF $21,345,

compared to just $803 in 2013.

Figure 10 shows that high-cost medicines represent a growing share of the total sales of patented medicines, rising steeply from 21.8% in 2013 to 57.5% in 2022. This growth was evident in all ranges of annual treatment costs ($10,000 to $20,000; $20,000 to $50,000; $50,000 to $100,000; and $100,000 and over), with medicines in the highest cost band climbing from 0.8% to 7.9% of sales over the same period. Despite the sharp increase in their share of costs, less than 1% of the population use these medicines.

FIGURE 10. SHARE OF SALES FOR HIGH-COST PATENTED MEDICINES BY ANNUAL TREATMENT COST, 2013 TO 2022



Share of sales (%)	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
$10K to $20K	9.1	9.8	11.0	12.9	14.4	15.1	17.6	19.2	19.9	17.1
$20K to $50K	10.5	11.7	13.4	15.6	20.2	19.4	18.7	18.4	19.8	20.7
$50K to $100K	1.4	3.2	7.7	6.9	5.2	5.8	8.6	10.4	12.4	11.8
$100K+	0.8	1.0	1.2	1.4	1.5	1.8	3.4	4.1	5.0	7.9
Total*	21.8	25.7	33.3	36.8	41.3	42.1	48.3	52.1	57.1	57.5
High-cost medicines	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
Cost ($millions)	$3,624	$4,284	$5,549	$6,141	$6,864	$6,996	$8,330	$9,124	$9,956	$10,587
Total no. of medicines	105	116	129	143	150	162	172	189	201	204
$10K to $20K	39	40	42	44	47	49	52	57	60	51
$20K to $50K	45	50	58	68	69	73	71	74	74	76
$50K to $100K	11	15	17	18	20	24	29	35	38	44
$100K+	10	11	12	13	14	16	20	23	29	33
Avg. treatment cost ($thousands)	$37.8	$41.4	$44.8	$43.5	$42.7	$45.8	$51.8	$53.9	$59.0	$63.3
Estimated treatment population (thousands)	167.2	186.9	222.4	254.1	284.8	285.8	331.3	349.8	370.3	366.7
Share of total Cdn population	0.48%	0.53%	0.62%	0.70%	0.77%	0.78%	0.88%	0.92%	0.97%	0.94%

Note: The methodology for this analysis was revised in 2018, and as such, historical results may not match those reported in earlier editions.

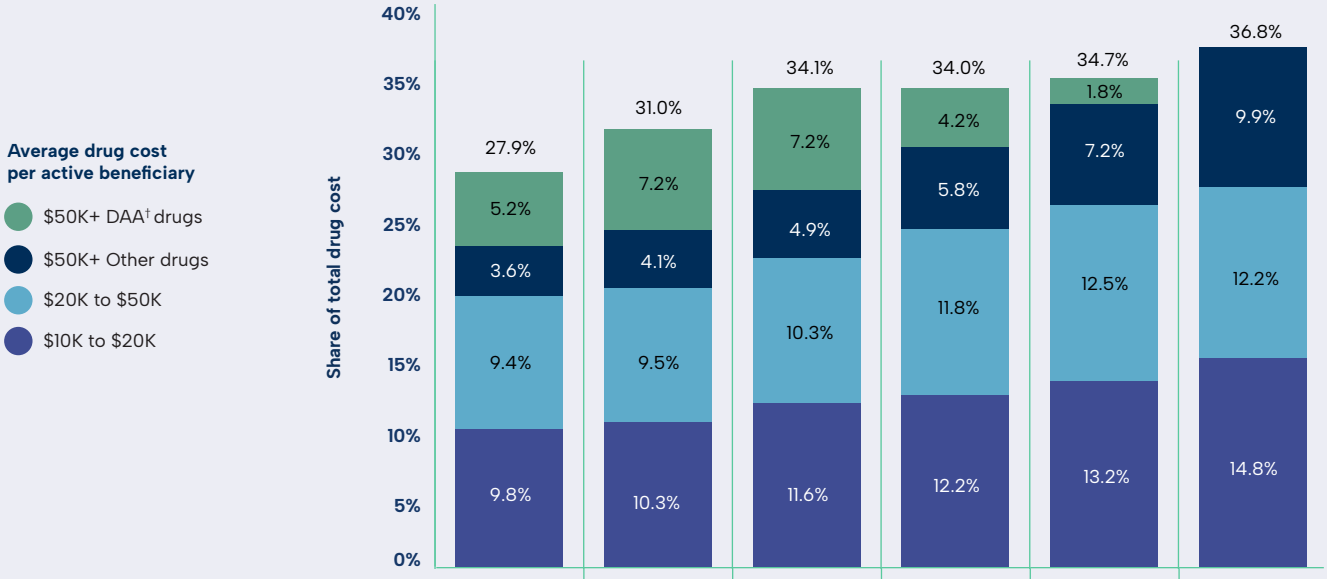
* Values may not add to totals due to rounding.

Data source: PMPRB; IQVIA Private Pay Direct Drug Plan database, 2013–2022

BRIEF INSIGHTS: HIGH-COST MEDICINES IN PUBLIC DRUG PLANS

High-cost medicines account for 36.8% of all public drug plan expenditures. This is lower than the share for patented medicines reported in Figure 10 because public plan costs also include non-patented generic and non-patented single-source medicines. Public plans reimbursed 144 high-cost medicines in fiscal year 2021-22, while private drug plans reimbursed 264 high-cost medicines in calendar year 2022.

FIGURE 11. TRENDS IN THE NUMBER AND SHARE OF HIGH-COST MEDICINES, NPDUIS PUBLIC DRUG PLANS*, 2016-17 TO 2021-22



	2016–17	2017–18	2018–19	2019–20	2020–21	2021–22
Total cost for high-cost medicines ($millions)	$2,347.4	$2,829.0	$3,288.3	$3,426.0	$3,483.9	$4,009.1
Total no. of medicines§	103	107	121	130	135	144
Share of active beneficiaries	1.73%	1.75%	1.72%	2.12%	2.51%	2.98%
Share of prescriptions	0.30%	0.34%	0.38%	0.40%	0.42%	0.49%

Note: High-cost medicines are defined as having an annual treatment cost greater than $10,000. If medicines reach this threshold in any given year, they are included in the count for all other years. Thus, the number and composition of high-cost medicines in any given year may vary depending on the time of analysis.

The number of oncology medicines and other high-cost medicines covered by public plans may be underestimated, as some are reimbursed through specialized programs, such as cancer care, that are not captured in the data.

Values may not add to totals due to rounding.

* British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon, and the Non-Insured Health Benefits (NIHB) Program. Results from 2020-21 do not include the NIHB program.

† DAA: Direct-acting antivirals for the treatment for hepatitis C, which were launched in 2014 and 2015. See earlier cost driver analysis (Figure 7) for more information.

‡ 2021-22 results included the cost share for >$50K DAA drugs (1.5%).

§ The total number of high-cost medicines reimbursed by the NPDUIS public drug plans is calculated using prescription drug utilization data, which includes claims for all medicines funded by public plans, and does not necessarily reflect the number of medicines listed on the formularies for these plans.

Data source: NPDUIS database, Canadian Institute for Health Information (fiscal year data)

[NPDUIS Report: *CompassRx 2021/22* (pre-publication results)]

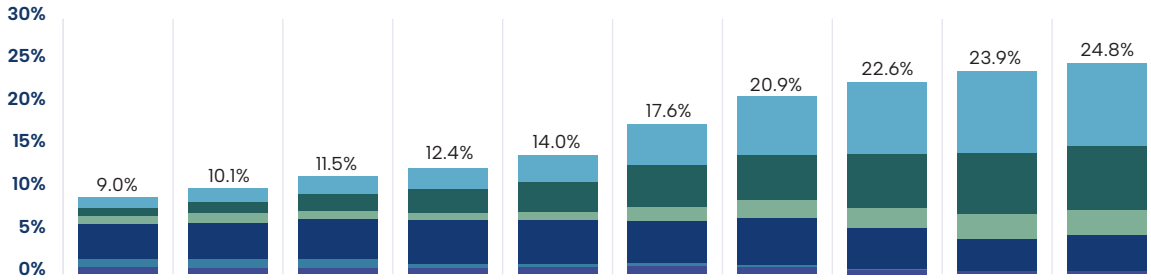
The shift toward higher-cost treatments is especially evident in oncology medicines. Figure 12 shows the share of total sales for patented oncology medicines by treatment cost based on a standard 28-day treatment regimen.[8]

The number of patented oncology medicines with 28-day treatment costs over $7,500 rose from 15 to 68 between 2013 and 2022, now accounting for 17.3% of total patented medicine sales.

As a result, the average treatment cost for oncology medicines in 2022 was $14,024, compared to $5,564 in 2013.

Many treatment regimens use multiple medicines resulting in even higher treatment costs per beneficiary. The dual pressures of increasing average treatment costs and growing utilization mean that this therapeutic area is likely to continue to grow as a proportion of patented medicine sales.

FIGURE 12. SHARE OF SALES FOR PATENTED ONCOLOGY MEDICINES BY 28-DAY TREATMENT COST, 2013 TO 2022



Share of sales (%)	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Other*	0.8	0.7	0.7	0.7	0.8	0.9	0.8	0.5	0.3	0.3
<$2.5K	1.0	1.0	1.0	0.5	0.4	0.4	0.3	0.1	0.1	0.1
$2.5K to $5.0K	4.1	4.3	4.8	5.1	5.1	4.9	5.5	4.8	3.7	4.2
$5.0K to $7.5K	0.9	1.1	0.9	0.9	1.0	1.7	2.0	2.3	3.0	2.9
$7.5K to $10.0K	0.9	1.3	2.0	2.8	3.5	4.9	5.4	6.4	7.1	7.5
$10.0K+	1.3	1.7	2.1	2.4	3.2	4.8	6.9	8.5	9.7	9.8
Total†	9.0	10.1	11.5	12.4	14.0	17.6	20.9	22.6	23.9	24.8
Oncology medicines	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
Cost ($millions)	$1,520	$1,678	$1,898	$2,050	$2,324	$2,939	$3,584	$3,947	$4,172	$4,559
Total no. of medicines	60	69	72	77	80	91	94	105	113	117
Other*	9	11	10	10	10	10	9	16	7	5
<$2.5K	13	12	12	10	10	8	7	6	7	6
$2.5K to $5.0K	15	16	17	17	17	18	18	19	21	20
$5.0K to $7.5K	8	12	12	14	13	15	16	16	20	18
$7.5K to $10.0K	7	9	10	13	15	19	21	22	25	24
$10.0K+	8	9	11	13	15	21	23	26	33	44
Avg. 28-day treatment cost	$5,564	$6,210	$6,656	$6,699	$7,039	$7,680	$9,320	$13,304	$13,478	$14,024
Estimated treatment population (thousands)	589.0	607.6	600.1	464.9	468.6	512.5	567.1	562.8	561.6	638.4
Share of total Cdn population	1.68%	1.71%	1.68%	1.28%	1.27%	1.37%	1.51%	1.48%	1.47%	1.61%

Note: The methodology for this analysis was revised in 2018 and 2019, and as such, historical results may not match those reported in earlier editions. These results reflect the total sales for patented medicines used in the treatment of cancer. While some of these medicines may also be used to treat other conditions, the data used for this analysis does not distinguish between indications, and thus, the reported sales may reflect some non-cancer use.

* Treatment costs for these medicines are not available.

† Values may not add to totals due to rounding.

Data source: PMPRB; CADTH pCODR

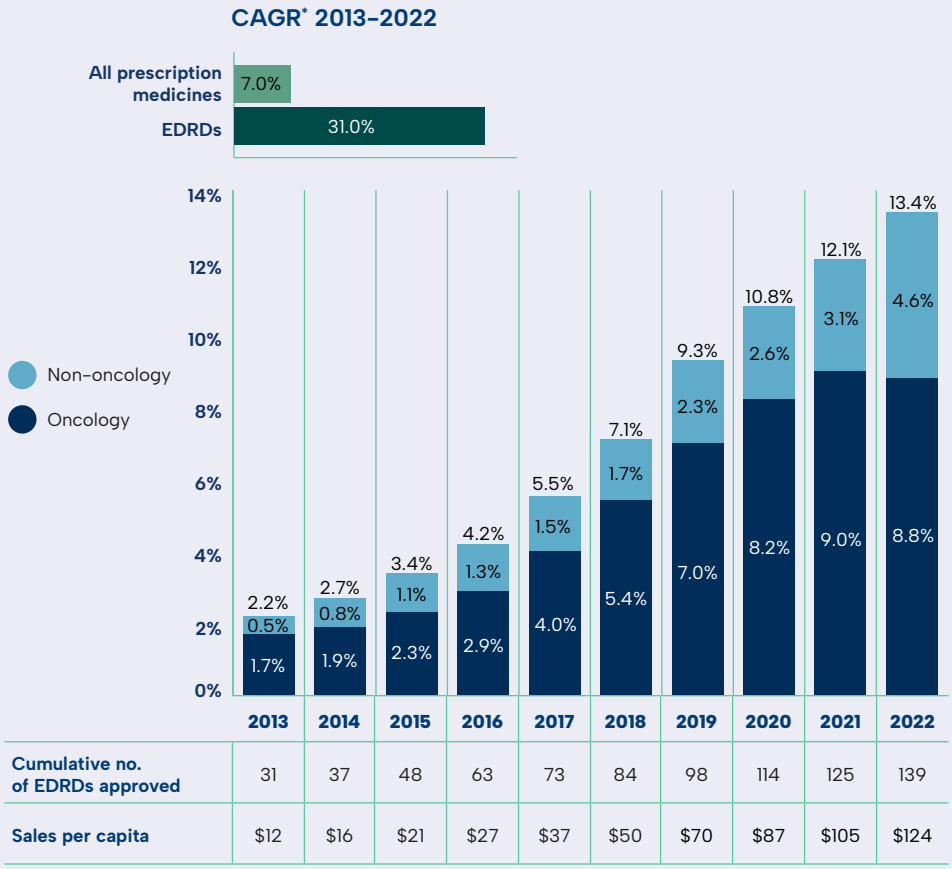
BRIEF INSIGHTS:

SPENDING ON EXPENSIVE DRUGS FOR RARE DISEASES

Expensive drugs for rare diseases (EDRDs) represent an increasing share of the Canadian pharmaceutical market, due to sales growth of existing medicines as well as the rapid pace of new launches, with at least 10 new EDRDs gaining approval in each year since 2015. Compound annual growth in EDRD sales over the past decade has been higher than the total pharmaceutical market, such that EDRDs made up 13.4% of sales in 2022. Two thirds of EDRD spending in 2022 was for oncology medicines.

Using NPDUIS drug plan data, it is estimated that 0.2% of public drug plans patients were reimbursed for an EDRD-related claim in 2022. These claims accounted for 6.8% of the total drug costs within public drug plans. This percentage does not include the use of oncology EDRDs in plans with alternative cancer coverage or EDRDs administered in hospitals, which are not recorded in the database, and may count some patients who received an orphan-designated medicine for one of its non-orphan indications.

FIGURE 13. EDRD SHARE OF THE PHARMACEUTICAL MARKET IN CANADA, ONCOLOGY AND NON-ONCOLOGY, 2013 TO 2022



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Cumulative no. of EDRDs approved	31	37	48	63	73	84	98	114	125	139
Sales per capita	$12	$16	$21	$27	$37	$50	$70	$87	$105	$124

Note: The data for this analysis was updated and, as such, historical results may not match those reported in previous editions.

For this analysis, EDRDs are defined as medicines with at least one orphan designation (by the US Food and Drug Administration or the European Medicines Agency) and estimated treatment costs exceeding $100,000 per year for non-oncology drugs or $7,500 per 28 days for oncology drugs.

* Compound annual growth rate (CAGR) of expenditures over the study period

Data source: PMPRB; MIDAS® database, 2013–2022, IQVIA (all rights reserved)

[NPDUIS Chartbook: *Expensive Drugs for Rare Diseases: Canadian Trends and International Comparisons, 2011–2020* – content updated for 2022]

TOP THERAPEUTIC CLASSES DRIVING SALES REVENUES

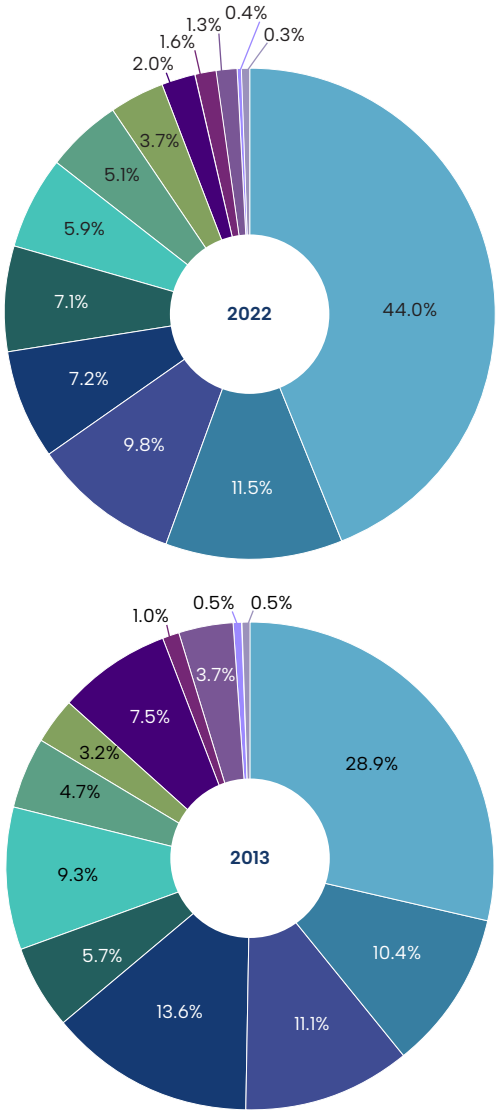
"Antineoplastics and immunomodulating agents", "alimentary tract and metabolism", and "general antiinfectives for systemic use and antiparasitic products" were the three top-selling therapeutic classes in 2022, accounting for close to two thirds of all patented medicine sales. The "antineoplastics and immunomodulating agents" class experienced a 3.3% increase in sales between 2021 and 2022 while "systemic hormonal preparations" had the greatest year-over-year decrease at -55.8%.

Figure 14 breaks down the sales of patented medicines in Canada by therapeutic class using level 1 of the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) system.[9] It compares the distribution of sales by therapeutic class in 2013 and 2022 and provides the rates of growth in sales for each class from 2021 to 2022.

The "antineoplastics and immunomodulating agents" class accounted for a much larger share of sales in 2022 (44.0%) than in 2013 (28.9%), as more oncology medicines entered the market over the past decade, many of which were high cost. By contrast, the share of sales held by "cardiovascular system" medicines decreased from 7.5% to 2.0% over the same period, continuing the trend observed in previous years.

FIGURE 14. SALES OF PATENTED MEDICINES BY MAJOR THERAPEUTIC CLASS, 2022

Share of Sales, 2022 versus 2013



Therapeutic class	2022 sales ($millions)	Growth: 2022/2021, $millions (rate in %)	2022 share of sales (%)
L: Antineoplastics and immunomodulating agents	$8,104.2	$257.2 (3.3%)	44.0%
A: Alimentary tract and metabolism	$2,112.6	$11.3 (0.5%)	11.5%
J: General antiinfectives for systemic use and P: Antiparasitic products*	$1,798.7	$197.9 (12.4%)	9.8%
N: Nervous system	$1,321.8	$164.9 (14.3%)	7.2%
B: Blood and blood forming organs	$1,298.2	-$22.8 (-1.7%)	7.1%
R: Respiratory system	$1,092.5	$380.3 (53.4%)	5.9%
S: Sensory organs	$944.2	$63.3 (7.2%)	5.1%
M: Musculo-skeletal system	$686.3	$21.8 (3.3%)	3.7%
C: Cardiovascular system	$370.2	-$4.2 (-1.1%)	2.0%
D: Dermatologicals	$294.6	-$16.7 (-5.4%)	1.6%
G: Genito-urinary system and sex hormones	$246.2	-$10.8 (-4.2%)	1.3%
V: Various	$74.2	-$9.5 (-11.3%)	0.4%
H: Systemic hormonal preparations	$59.5	-$75.0 (-55.8%)	0.3%
All therapeutic classes†	**$18,403.0**	**$957.7**	**100%**

* Medicines that stop reporting their sales to the PMPRB can factor into growth rates for the relevant therapeutic areas. Please refer to Figures 5 and 6 for a discussion on medicines that exited the patented market in 2022.

† These groups have been combined for reasons of confidentiality.

‡ Values may not add to totals due to rounding.

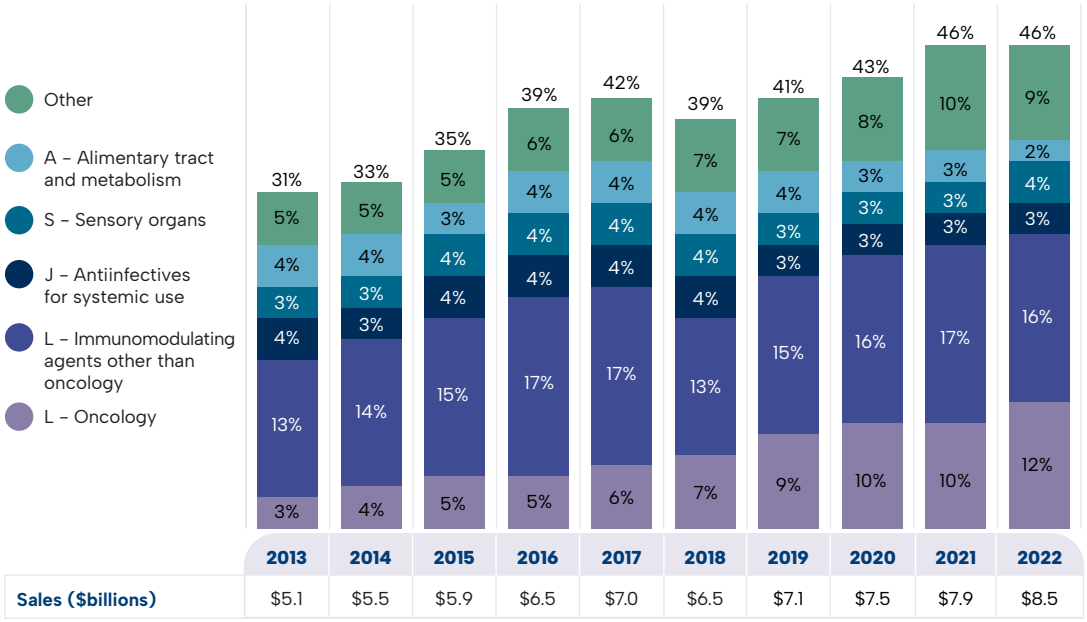
Data source: PMPRB

BIOLOGIC MEDICINES

Biologic medicines, many of which are in the high-cost category, capture a substantial share of the Canadian market. These medicines accounted for 46% of patented medicine sales in 2022, with the top three biologics alone representing more than 20% of sales. Figure 15 breaks down the annual share of sales for biologic patented medicines by major therapeutic class.

Although the share of biologic medicine sales has increased in many therapeutic classes, "immunomodulating agents other than oncology" had the highest uptake over the study period. Oncology medicines also represent a steadily growing share of the biologics market, increasing from 3% of patented medicine sales in 2013 to 12% in 2022.

FIGURE 15. BIOLOGIC MEDICINE SHARE OF PATENTED MEDICINE SALES BY THERAPEUTIC CLASS*, 2013 TO 2022



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Sales ($billions)	$5.1	$5.5	$5.9	$6.5	$7.0	$6.5	$7.1	$7.5	$7.9	$8.5

Note: Values may not add to totals due to rounding.

* Level 1 of Anatomical Therapeutic Chemical (ATC) classification system maintained by the World Health Organization.

Data source: PMPRB

BRIEF INSIGHTS: BIOSIMILAR UPTAKE

Given the high use and cost of biologics in Canada, biosimilars offer an opportunity for significant cost savings, with list price discounts ranging from 25% to 50% off the reference biologic.[i] However, biosimilar substitution has more complexities than traditional generics as they are not considered identical to their originator medicines, but rather highly similar versions, and Health Canada's authorization of a biosimilar is not a declaration of equivalence to the originator biologic.

Recently, an increasing number of Canadian payers have undertaken initiatives to encourage switching from biologics to biosimilars with an aim of increasing biosimilar uptake. Results for the biosimilars targeted by these initiatives in 2022 show positive signs in terms of increased utilization. In British Columbia, the first Canadian province to implement a biosimilar switching initiative, biosimilars now account for 90% of the infliximab market, contributing to the increase in uptake observed nationally in recent years.

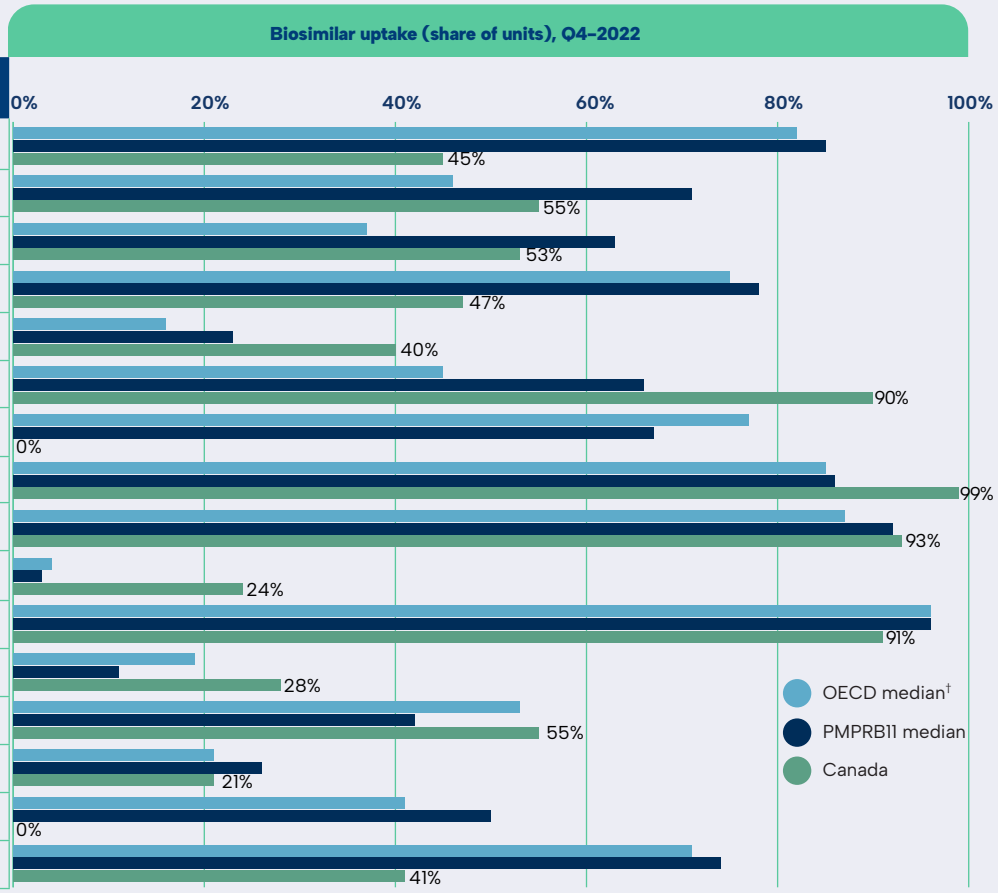
Biosimilars accounted for 45% of the total Canadian infliximab market in Q4-2022, compared to only 8% in Q4-2018, while shares in the etanercept and insulin glargine markets have increased to 53% and 40%, respectively (Figure 16). The recent market entry of biosimilars for adalimumab and rituximab have achieved sizable uptake for these two markets, reaching 55% and 47% of units sold by the last quarter of 2022, respectively.

While these results demonstrate growing use of biosimilars, biosimilar uptake in Canada is moderate compared to international markets, particularly for high-selling products. Canada's 45% biosimilar share of infliximab in 2022 was well below the OECD and PMPRB11 medians, at 82% and 85% respectively (Figure 17).

Continued on next page...

FIGURE 16. BIOSIMILAR SHARE OF UNITS BY MEDICINE, CANADA, THE OECD, AND THE PMPRB11, Q4-2022

Biologic medicine	Sales in Canada, 2022 ($millions)
Infliximab	$1,227
Adalimumab	$875
Etanercept	$240
Rituximab‡	$217
Insulin glargine	$208
Trastuzumab‡	$118
Epoetin alfa*	$116
Pegfilgrastim*	$106
Bevacizumab‡	$97
Insulin aspart	$92
Filgrastim*	$90
Insulin lispro	$80
Enoxaparin	$54
Somatropin	$45
Follitropin alfa*	$23
Teriparatide	$9



Note: The 2022 update uses PMPRB11 comparator countries in place of PMPRB7.

* Generally used to treat acute conditions.

† Canada is excluded from the median OECD value.

‡ Mainly used for treatment of oncology indications and administrated in hospitals in Canada.

Data source: MIDAS® database, prescription retail and hospital markets, 2022, IQVIA (all rights reserved)

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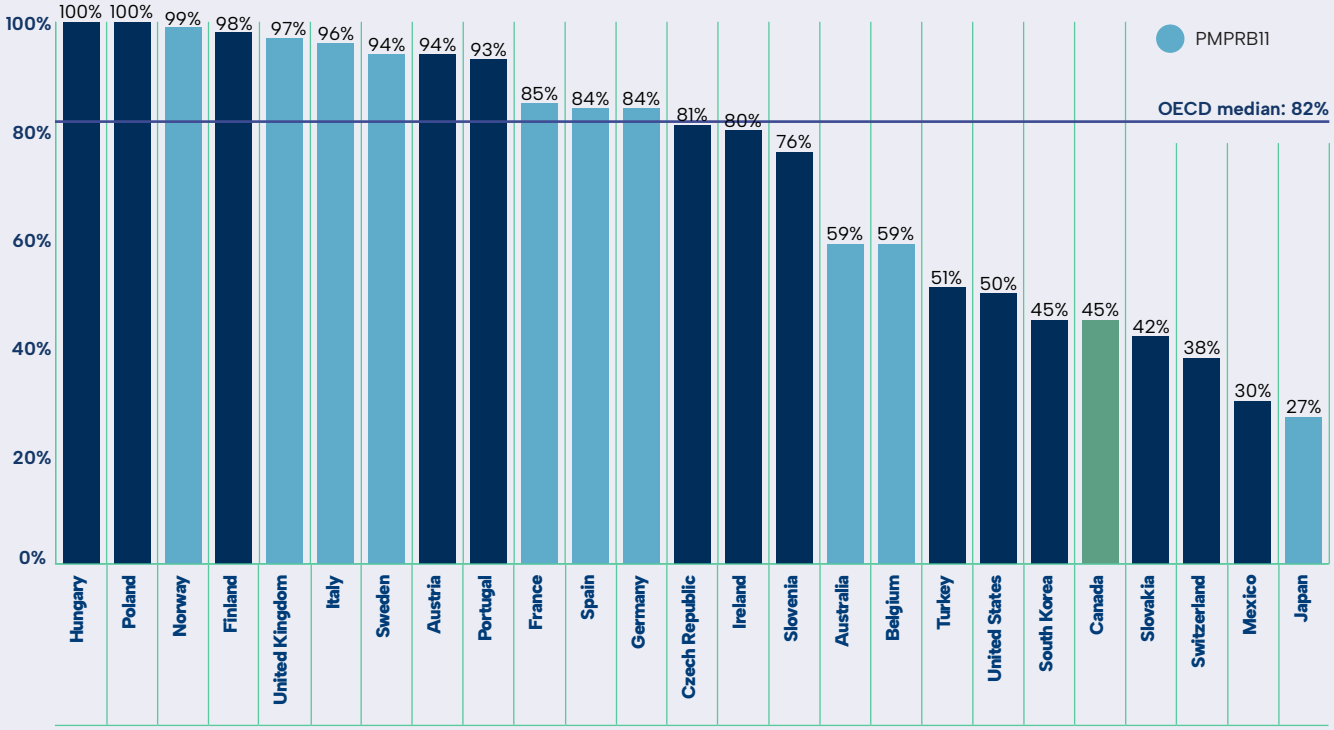
FIGURE 17. UPTAKE OF INFLIXIMAB BIOSIMILARS BY SHARE OF UNITS, OECD, Q4-2022



Note: Countries with limited data were excluded from the analysis. The 2022 update highlights PMRPB11 countries instead of PMPRB7.

Data source: MIDAS® database, prescription retail and hospital markets, Q4-2022, IQVIA (all rights reserved)

i PMPRB. 2021. Poster: Biosimilars in Canada: building momentum in the wake of recent switching policies. Presented at CADTH Symposium; November 2021. Available: **https://www.canada.ca/en/patented-medicine-prices-review/services/npduis/analytical-studies/slide-presentations/biosimilars-cadth-2021.html**

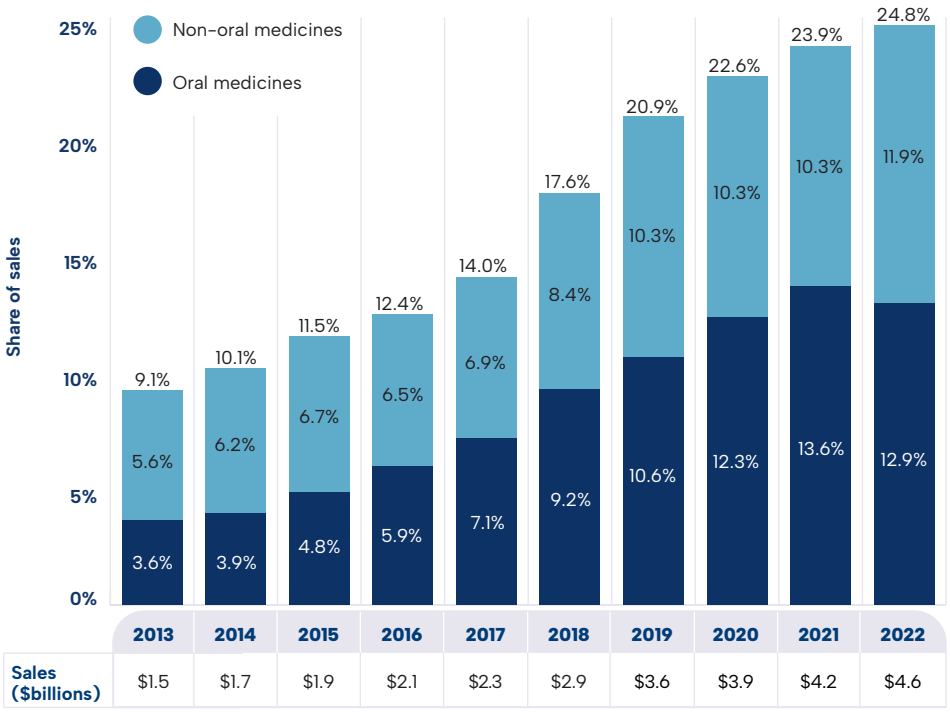
[NPDUIS Chartbook: *Biologics in Canada. Part 1: Market Trends, 2018* – graphs updated for 2022]

ONCOLOGY MEDICINES

Figure 18 illustrates the growth in the sales of patented oncology medicines since 2013. In 2022, oncology medicines accounted for 24.8% of total patented medicine sales, close to triple the 2013 share of 9.1%.

Oral forms of cancer treatment are a noteworthy emerging segment, representing more than half of all oncology medicine sales and 12.9% of the patented medicine market in 2022, compared to just 3.6% in 2013.[10]

FIGURE 18. ONCOLOGY MEDICINE SHARE OF PATENTED MEDICINE SALES BY FORMULATION, 2013 TO 2022



Note: These results reflect the total sales for patented medicines used in the treatment of cancer. While some of these medicines may also be used to treat other conditions, the data used for this analysis does not distinguish between indications, and thus, the reported sales may reflect some non-oncology use.

Values may not add to totals due to rounding.

Data source: PMPRB

ENDNOTES

5 Sales and price information do not take into account indirect discounts provided to third party payers, such as product listing agreements.

6 All statistical results for patented medicines reported in this section are based on data submitted by rights holders as of March 2023. On occasion, rights holders may revise previously submitted data or provide data not previously submitted. This can appreciably affect the statistics in this section. To account for this possibility, the PMPRB reports recalculated sales figures (see "Trends in the Sales of Patented Medicines"), price and quantity indices (see "Price Trends and Utilization of Patented Medicines"), and foreign-to-Canadian price ratios (see "Comparison of Canadian Prices to Foreign Prices") for the five years preceding the current Annual Report year. All recalculated values reflect currently available data. If the data has been revised, the values reported here may differ from those presented in earlier Annual Reports.

7 The cost driver analysis used here follows the approach detailed in the PMPRB report *The Drivers of Prescription Drug Expenditures: A Methodological Report, 2013*. As this model uses various measures to isolate the factors contributing to growth, the net change reported here may differ slightly from the reported overall growth in the patented medicines market.

8 There is some overlap in the medicines reported in Figures 10 and 12, as the oncology medicines that exceeded $10,000 in annual treatment costs are considered in both graphs.

9 In this report, medicines are classified according to the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) classification system. This is a scientific, hierarchical system based on the principal therapeutic use and chemical composition of a medicine. The first level classifies medicines according to the element of human anatomy with which they are primarily associated.

10 The results reported for the high-cost, biologic, and oncology market segments are not mutually exclusive, as many oncology medicines are biologics and many biologics are high-cost medicines.

PRICE TRENDS

The PMPRB uses the Patented Medicines Price Index (PMPI) to monitor trends in the prices of patented medicines. The PMPI measures the average year-over-year change in the ex-factory prices of patented medicines sold in Canada using a sales-weighted average of price changes at the level of individual medicines.[11] This is similar to the approach Statistics Canada uses to construct the Consumer Price Index (CPI). The PMPI is based on an average transaction price and sales information submitted by rights holders for a six-month period.

The PMPI only measures the sales growth attributable to changes in the prices of patented medicines. It does not measure changes in the use of patented medicines; this is measured by the quantity index or PMQI (see "Utilization of Patented Medicines"). Nor does it measure the cost impact of changes in prescribing patterns or the introduction of new medicines.

The *Patent Act* requires the PMPRB to consider changes in the CPI, among other factors, in determining whether the price of a patented medicine is excessive. Figure 19 compares year-over-year changes in the PMPI to corresponding changes in the CPI from 2003 to 2022.

The PMPI is reported based on two measures: the national average transaction price, which is a net price; and the national list price, which is a gross price.[12] Both measures are reported to the PMPRB by rights holders. General price inflation, as measured by the CPI, has exceeded the average increase in the prices of patented medicines almost every year since 2003. In 2022, the CPI rose by 6.8%, while the national average transaction price and the national list price PMPIs increased by 0.8% and 0.9%, respectively.

FIGURE 19. ANNUAL RATE OF CHANGE, PATENTED MEDICINES PRICE INDEX (PMPI) AND CONSUMER PRICE INDEX (CPI), 2003 TO 2022

Rate of change (%)	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
CPI	2.8	1.8	2.2	2.0	2.2	2.3	0.3	1.8	2.9	1.5	0.9	2.0	1.1	1.4	1.6	2.3	1.9	0.7	3.4	6.8
PMPI change – National Average Transaction Price	0.1	0.7	0.5	-0.2	0.0	-0.1	0.2	-0.5	-0.1	0.3	-0.1	0.0	0.0	-0.6	-0.2	-0.3	1.0	0.6	0.4	0.8
PMPI change – National List Price	0.6	1.0	1.2	0.1	1.4	2.9	1.3	2.4	1.4	1.2	1.4	0.8	0.2	0.3	0.8	0.1	1.3	1.6	0.5	0.9

Note: To account for revised submissions from rights holders, price and quantity indices are recalculated for the five years preceding the current Annual Report year. If the data has been revised, the values reported here may differ from those presented in earlier Annual Reports.

Data source: PMPRB; Statistics Canada

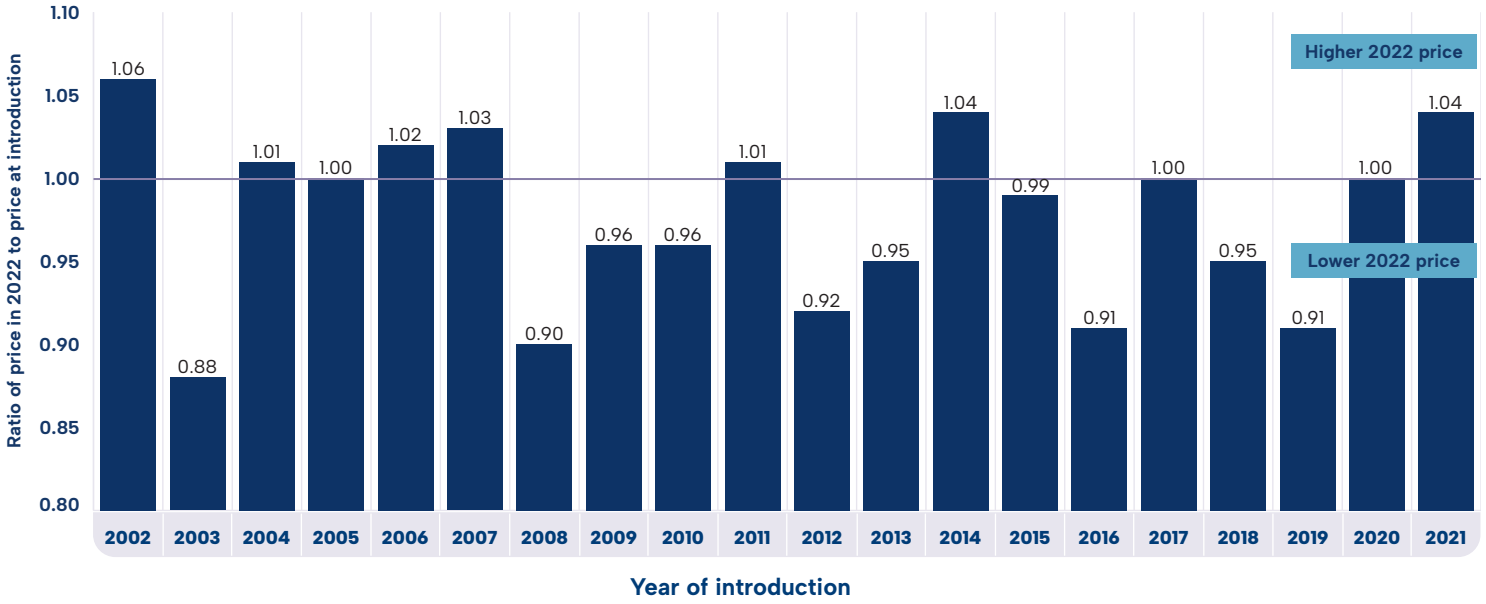
PRICE BEHAVIOUR AFTER INTRODUCTION

Do the average prices of patented medicines change much in the years after entry into the Canadian market? To answer this question, Figure 20 provides the average ratio of the 2022 average transaction price to the introductory price (the price at which the medicine was sold in its first year on the Canadian market) for medicines that entered the market each year since 2002.

The results suggest that over the last two decades, average transaction prices of patented medicines have remained relatively stable, with 2022 prices being on average 4% higher than the introductory price.[13] The average ratios for medicines introduced since 2002 ranged between 12% lower and 6% higher than their introductory prices depending on the introductory year.

A parallel analysis using list prices is available in Appendix 3.

FIGURE 20. AVERAGE RATIO OF 2022 PRICE TO INTRODUCTORY PRICE, BY YEAR OF INTRODUCTION



Note: This analysis is based on average transaction prices. For an alternative version based on list prices, see Appendix 3.
Data source: PMPRB

PRICE CHANGE BY COUNTRY

In 2022, in accordance with the Act and the Regulations, rights holders reported publicly available prices of patented medicines for 11 comparator countries (PMPRB11): Australia, Belgium, France, Germany, Italy, Japan, Spain, Sweden, Norway, the Netherlands, and the United Kingdom (UK).

The PMPRB uses this information to

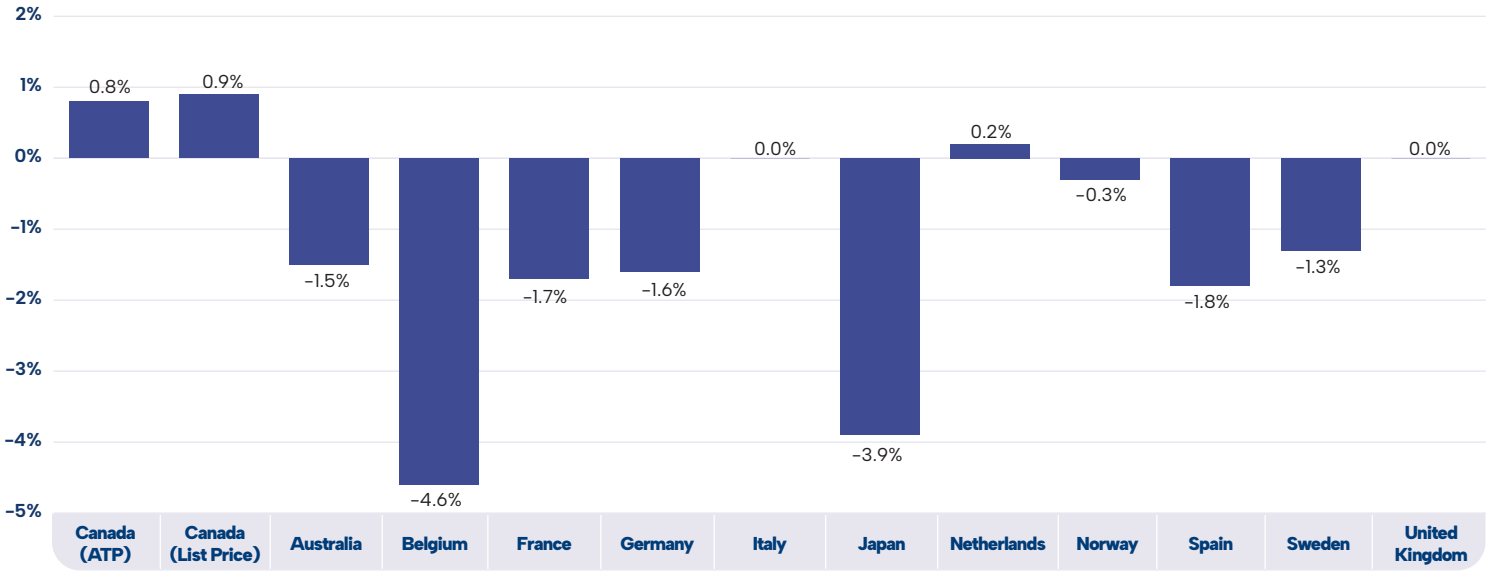
- conduct international price comparison tests; and
- compare the Canadian prices of patented medicines to those prevailing in other countries.

Figure 21 gives the average annual rates of price change for Canada and each of the PMPRB11 countries. These results were obtained by applying the PMPI methodology (with weights based on Canadian sales patterns) to the international price data that rights holders submitted to the PMPRB.

In 2022, Canadian average transaction prices saw a slight increase of 0.8%, while prices in the Netherlands, Italy, and the UK remained relatively steady. All other PMPRB11 countries saw average price decreases, most notably in Belgium (–4.6%) and Japan (–3.9%). These results are consistent with a long-term tendency for patented medicine prices to slowly fall over time in most comparator countries.

The foreign market results are based on publicly available gross prices, namely ex-factory price information (generally for the retail customer class) submitted by rights holders to the PMPRB. The Canadian rate of change, however, is based on net prices, namely actual average transaction prices net of rebates and discounts provided by manufacturers to their direct customers. To account for this difference, a rate of change for Canadian list prices is also provided as a point of comparison. In 2022, list prices in Canada increased by 0.9%.

FIGURE 21. ANNUAL AVERAGE RATES OF PRICE CHANGE, CANADA AND THE PMPRB11, 2022



Note: Prices for Australia, Belgium, Japan, Spain, Norway, and the Netherlands were sourced from the IQVIA MIDAS® database.
Data source: PMPRB; MIDAS® database, 2022, IQVIA (all rights reserved)

ENDNOTES

[11] These calculations are performed at the level defined by Health Canada's Drug Identification Number (DIN). Each DIN represents a unique combination of active ingredient(s), dosage form, strength(s), brand, and manufacturer.

[12] The national average transaction price is the Canadian "average price per package" or "net revenue from sales of each dosage form" referred to in s. 4(1)(f)(i) and 4(4) of the *Patented Medicines Regulations*; it does not include indirect rebates and discounts offered by rights holders such as certain rebates to provinces or insurers. The national list price is the gross Canadian "publicly available ex-factory price" referred to in s. 4(1)(f)(ii) of the *Patented Medicines Regulations*.

[13] This refers to the behaviour of prices on average. There may be instances where individual prices have risen or fallen substantially since introduction.

COMPARISON OF CANADIAN PRICES TO FOREIGN PRICES

Tables 7 and 8 provide detailed statistics comparing the foreign prices of patented medicines to their Canadian prices. Each table provides two sets of average price ratios. These are differentiated according to the method by which foreign prices were converted to their Canadian dollar equivalents. The tables also give the numbers of strengths and dosage forms of medicines (DINs) and the volume of sales encompassed by each reported price ratio.[14]

The average price ratios given in Tables 7 and 8 are sales-weighted arithmetic means of price ratios obtained for individual DINs, with weights based on Canadian sales patterns. Average price ratios constructed in this way provide answers to questions such as:

How much more/less would Canadians have paid for the patented medicines they purchased in 2022 had they paid Country X prices rather than Canadian prices?

For example, Table 7 states that the 2022 average France-to-Canada price ratio for medicines available in both countries was 0.75. This means Canadians would have paid 25% less for the patented medicines they purchased in 2022 if they had paid French prices.

For many years, the PMPRB has reported average foreign-to-Canadian price ratios with foreign prices converted to their Canadian dollar equivalents by means of market exchange rates (more exactly, the 36-month moving averages of market rates the PMPRB normally uses in applying its Guidelines). Tables 7 and 8 also report foreign-to-Canadian price ratios with currency conversion at purchasing power parity (PPP). The PPP between any two countries measures their relative costs of living expressed in units of their own currencies. In practice, cost of living is determined by pricing out a standard basket of goods and services at the prices prevailing in each country.

Because PPPs are designed to represent relative costs of living, they offer a simple way to account for differences in overall national price levels when comparing individual prices, incomes, and other monetary values across countries. When applied to the calculation of average foreign-to-Canadian price ratios, they produce statistics answering questions such as:

How much more/less consumption of other goods and services would Canadians have sacrificed for the patented medicines they purchased in 2022 had they lived in Country X?

Questions such as this cannot be answered by simply comparing the prices of medicines. Rather, one must first calculate what each price represents in terms of goods and services foregone. PPPs are designed for such purposes.

BILATERAL PRICE COMPARISONS

Table 8 provides bilateral comparisons of list prices in each of the PMPRB11 countries to average transaction prices in Canada. Focusing on the results with currency conversion at market exchange rates, it appears that, as in previous years, Canadian prices were typically within the range of prices observed in comparator countries. Prices reported for Australia, Belgium, France, Sweden, Norway, the Netherlands, and Italy were lower than Canadian prices, while prices in Germany were on par with Canada. Three countries—Japan, Spain, and the UK—continued to report prices that were higher than Canada. Year-to-year changes in these ratios may be influenced by variations in international exchange rates.

It is important to note that it is not always possible to find a matching foreign price for every strength and dosage form of a patented medicine sold in Canada. Table 7 indicates how often an international price comparison was available for each of the comparator countries. For example, of the 1,112 DINs that reported a patent to the PMPRB in 2022 and had Canadian sales available at the time of analysis, 48% had a publicly available ex-factory price for France while 74% had a price for Germany. In this case, it is considered to constitute the international median price, as per the PMPRB's methodology.

When international differences in the cost of living are considered (using PPP), the average price ratios indicate that Canadians incurred a larger consumption cost for the patented medicines they purchased in 2022 than residents of Australia, France, Sweden, and Norway.

This analysis uses average transaction prices for the Canadian market. A parallel analysis using Canadian list prices is available in Appendix 3.

TABLE 7. AVERAGE FOREIGN-TO-CANADIAN PRICE RATIOS, BILATERAL COMPARISONS, CANADA AND THE PMPRB11, 2022

	Canada	Australia	Belgium	France	Germany	Italy	Japan	Netherlands	Norway	Spain	Sweden	United Kingdom
At market exchange rates												
Average price ratio 2022	1.00	0.76	0.88	0.75	1.00	0.99	1.11	0.99	0.91	1.01	0.86	1.03
Average price ratio 2021	1.00	0.71	0.88	0.74	1.00	0.98	0.90	0.77	0.88	0.96	0.88	1.00
At purchasing power parities												
Average price ratio 2022	1.00	0.71	1.06	0.93	1.18	1.36	1.30	1.10	0.76	1.40	0.88	1.16
Average price ratio 2021	1.00	0.67	1.03	0.90	1.19	1.33	0.98	0.86	0.82	1.32	0.90	1.14
Number of patented medicines compared 2022 (DINs)	1,112*	522	620	532	818	690	481	775	779	725	630	783
Sales ($millions)	$18,403.2	$14,333.6	$14,419.9	$11,827.3	$15,769.2	$14,830.9	$12,363.4	$15,672.8	$15,724.0	$14,731.0	$12,110.4	$15,587.5

Note: 2021 prices for Australia, Belgium, Japan, Spain, Norway, and the Netherlands were sourced from IQVIA'S MIDAS® database. This analysis is based on average transaction prices in Canada. For an alternative version using list prices in Canada, see Appendix 3.

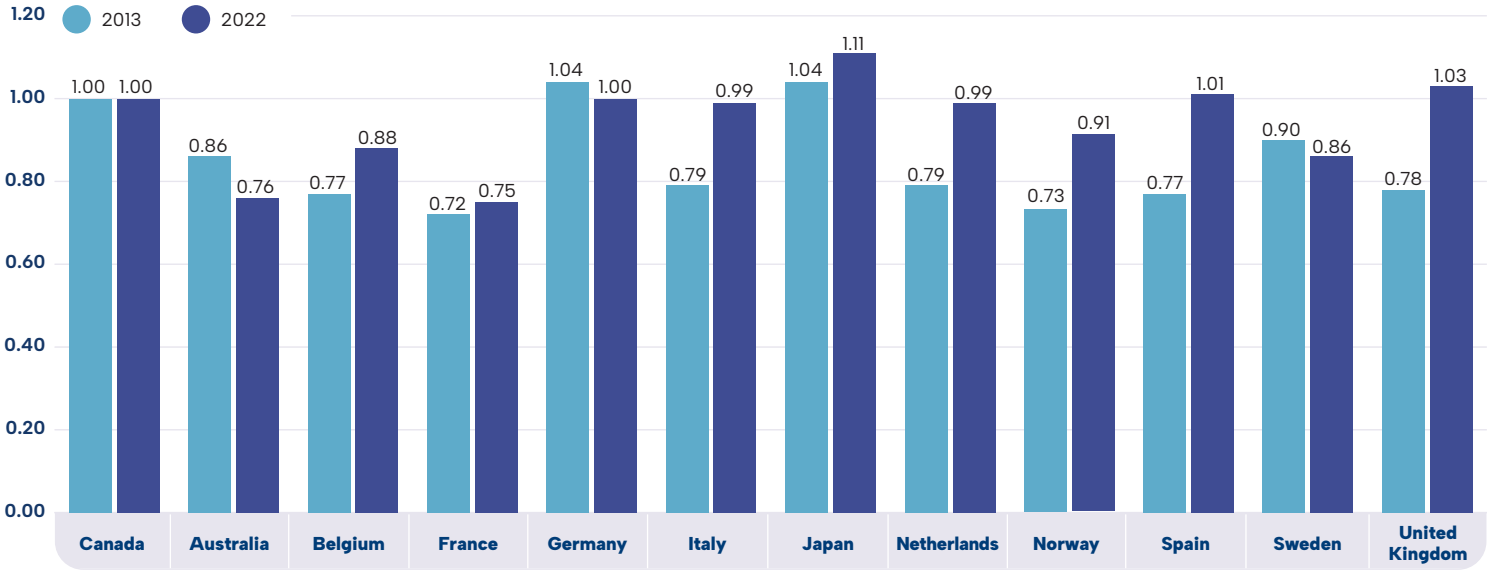
* Consistent with the methodology used throughout the Pharmaceutical Trends section, only medicines that reported to the PMPRB in 2022 and had available Canadian sales data at the time of the analysis were considered here. This is a subsection of the total number of medicines that reported to the PMPRB in 2022 and, as such, may not match the total reported in Table 4.

Data source: PMPRB; MIDAS® database, 2022, IQVIA (all rights reserved)

Figure 22 compares the 2022 foreign-to-Canadian price ratios (at market exchange rates) to those in 2013. While the ratios for Australia, Germany, and Sweden decreased over the past decade, price ratios for the eight other PMPRB11 comparators increased compared to Canada. In 2013, only three countries had a price ratio equal to or greater than 0.90, but by 2022 this number had increased to seven.

This analysis uses average transaction prices for the Canadian market. A parallel analysis using Canadian list prices is available in Appendix 3.

FIGURE 22. AVERAGE FOREIGN-TO-CANADIAN PRICE RATIOS, CANADA AND THE PMPRB11, 2013 AND 2022



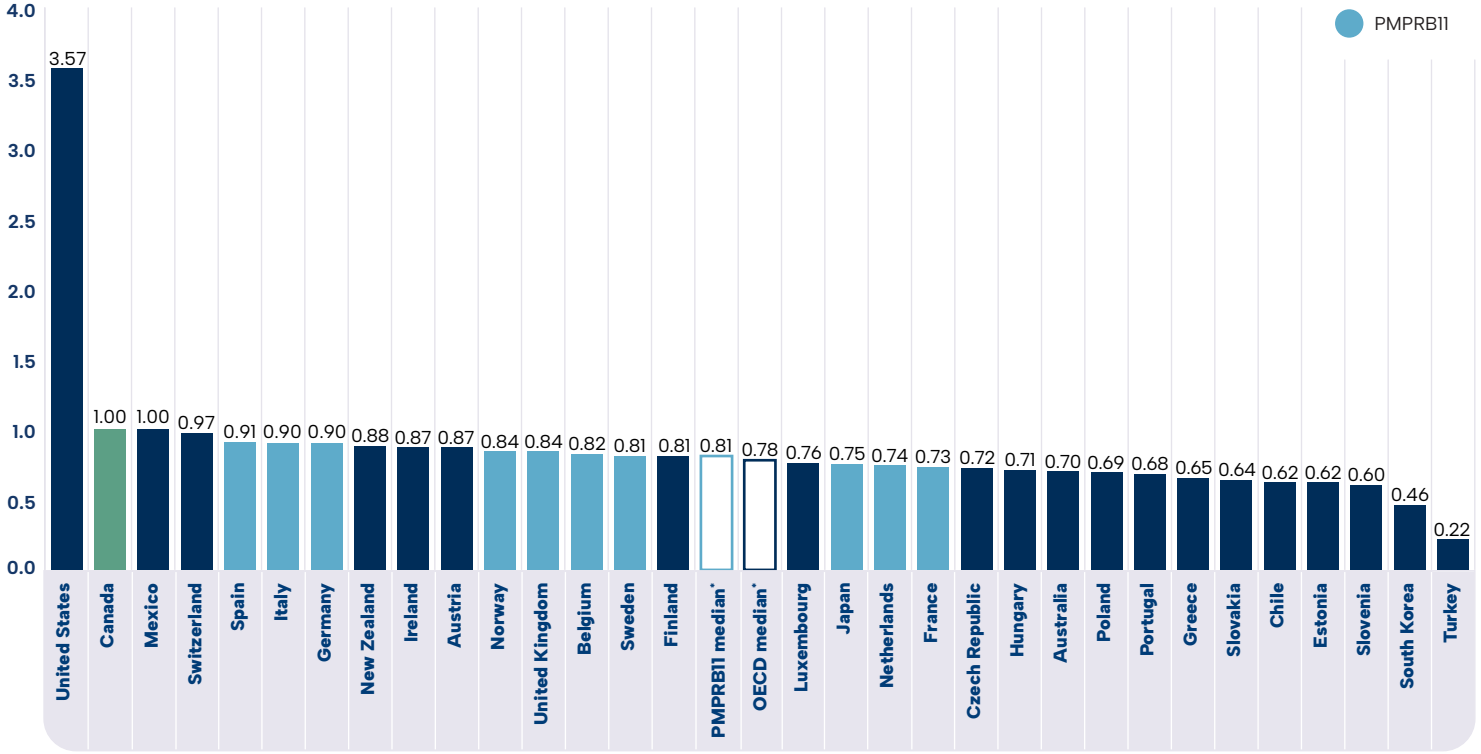
Note: 2013 prices for Australia, Belgium, Japan, Spain, Norway, and the Netherlands are sourced from the IQVIA MIDAS® database. This analysis is based on average transaction prices in Canada. For an alternative version using list prices in Canada, see Appendix 3.

Data source: PMPRB, MIDAS® database, 2013 and 2022, IQVIA (all rights reserved)

If a patented medicine is being sold in one or more of the PMPRB11 countries, the rights holder must report the publicly available ex-factory prices to the PMPRB for each class of customer.[15] Using this data, Figure 22 provides sales-weighted bilateral ratios comparing Canadian average transaction prices against foreign list prices. In order to assess how Canada compares to a basket of countries beyond the PMPRB11, Figure 23 uses Canadian and international prices reported in the IQVIA MIDAS® database at the ex-factory manufacturer level, reflecting all sales to the pharmacy and hospital sectors.[16] Note that the results presented in Figures 22 and 23 will differ somewhat due to the use of different data sources.

The international price comparisons reported in Figure 23 provide a bilateral price comparison for all countries in the Organisation for Economic Co-operation and Development (OECD) with available MIDAS® data. The average foreign-to-Canadian price ratios are calculated using the same approach employed to produce the ratios presented in Figure 22. These are Canadian sales-weighted arithmetic averages of the corresponding foreign-to-Canadian price ratios for individual medicines. As shown in Figure 23, median OECD prices are, on average, approximately 22% lower than price levels in Canada, which are the second highest among the 31 countries.

FIGURE 23. AVERAGE FOREIGN-TO-CANADIAN PRICE RATIOS, PATENTED MEDICINES, OECD, 2022



* Calculated at the medicine level for medicines with prices available in at least three foreign markets.

Data source: PMPRB; MIDAS® database, 2022, IQVIA (all rights reserved)

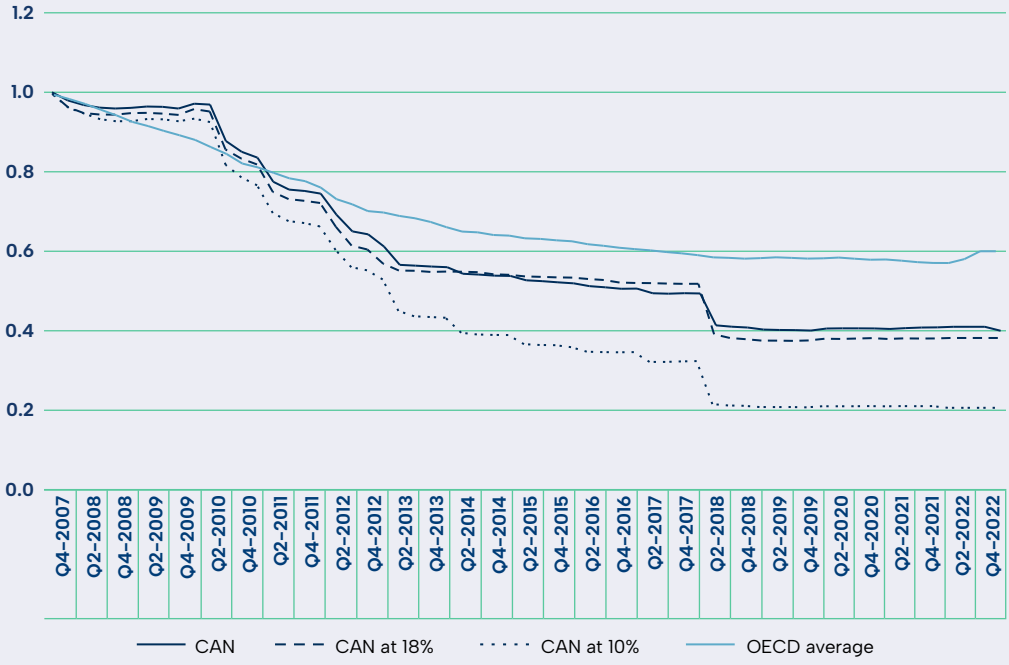
BRIEF INSIGHTS: TRENDS IN THE PRICE OF GENERIC MEDICINES

The average price of generic medicines in Canada has dropped substantially, by 60% in Q4-2022 relative to price levels in 2007 (Figure 24). This was the fourth-highest rate of price reduction compared to the PMPRB11 markets, following Australia, Japan, and Germany. Since the end of 2018, Canadian average prices have had little variance.

The most recent Canadian generic pricing policy, implemented in 2018, had brought Canadian generic prices closer in line with average prices in the OECD.

Despite this shift, Canadian prices were still third highest in the PMPRB11 in the last quarter of 2022, behind only Japan and Spain (Figure 25). The median PMPRB11 country, France, had average prices 22% lower. In the broader OECD, median prices were 31% lower than in Canada, and just six other countries had higher average generic prices.

FIGURE 24. PRICE INDICES AND GENERIC PRICE REDUCTIONS, CANADA AND THE PMPRB11, Q4-2007 TO Q4-2022



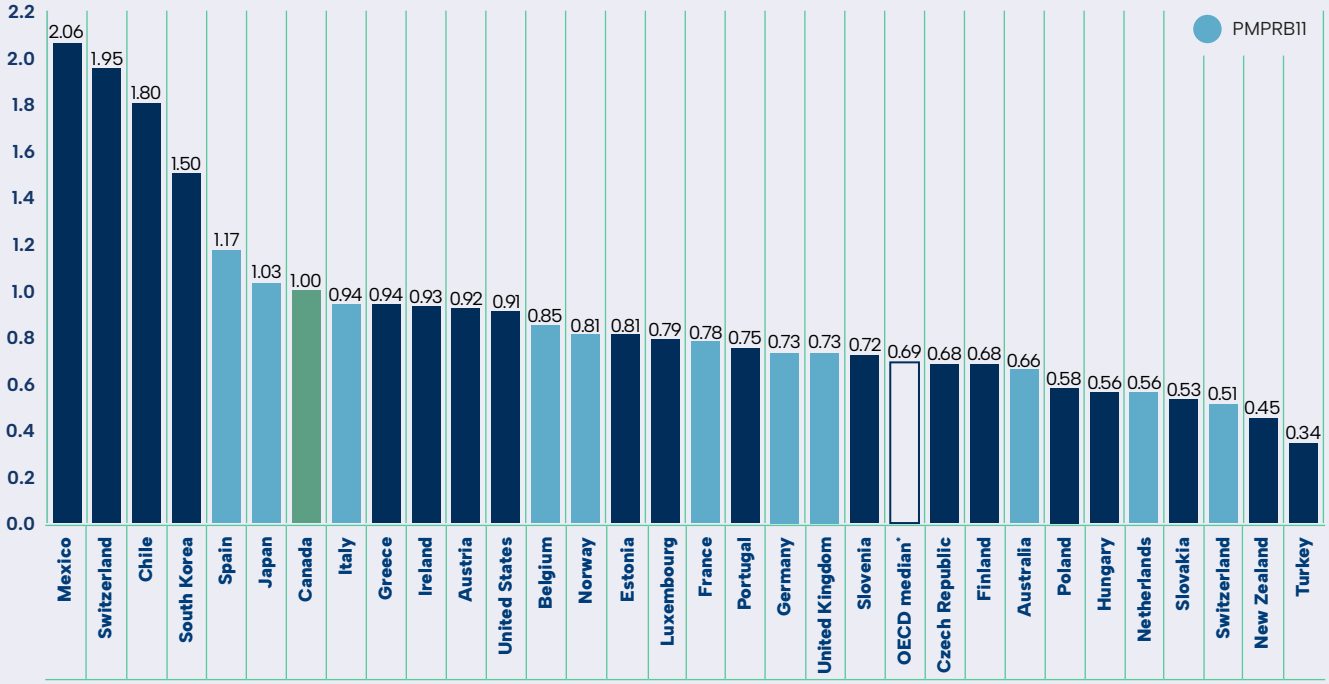
Generic price reduction Q4-2007 to Q4-2022	
Australia	-86%
CAN at 10%	-80%
Japan	-64%
CAN at 18%	-62%
Germany	-60%
Canada	-60%
United Kingdom	-57%
Spain	-46%
France	-45%
OECD average	-40%
Belgium	-38%
Italy	-28%
Sweden	-26%
Norway	-11%

Note: The term "generic" used in this analysis includes both patented and non-patented generic medicines. Results are based on manufacturer ex-factory list prices in the national retail markets. The analysis was restricted to oral solid generic medicines that had been on the market for at least one year. CAN at 18% and 10% refer to the 67 generic medicines reduced to 18% and 10% of their brand reference prices through the generic pricing policy introduced in April 2018. The Netherlands was excluded due to incomplete historical data.

Data source: MIDAS® database, October–December 2007 to October–December 2022, IQVIA (all rights reserved)

Continued on next page...

FIGURE 25. FOREIGN-TO-CANADIAN PRICE RATIOS FOR GENERIC MEDICINES, OECD, Q4-2022



* The OECD median does not necessarily represent the median result for the individual countries reported in this graph, as it is calculated at the medicine level for generics with prices available in at least three foreign markets.

Data source: MIDAS® database, October–December 2022, IQVIA (all rights reserved)

[NPDUIS Report: *Generics360, 2018* – graphs updated to 2022]

MULTILATERAL PRICE COMPARISONS

Table 8 provides average foreign-to-Canadian price ratios using several multilateral measures of foreign prices. The median international price (MIP) is the median of list prices observed among the PMPRB11. Other multilateral price ratios compare the minimum, maximum, and simple mean of PMPRB11 foreign prices to the Canadian average transaction price.

Focusing on the results based on market exchange rates, the average MIP-to-Canadian price ratio was 0.96 for the PMPRB11 in 2022, a slight increase over 2021 (Figure 26).

Both Table 8 and Figure 26 use average transaction prices for the Canadian market. Parallel analyses using Canadian list prices are available in Appendix 3.

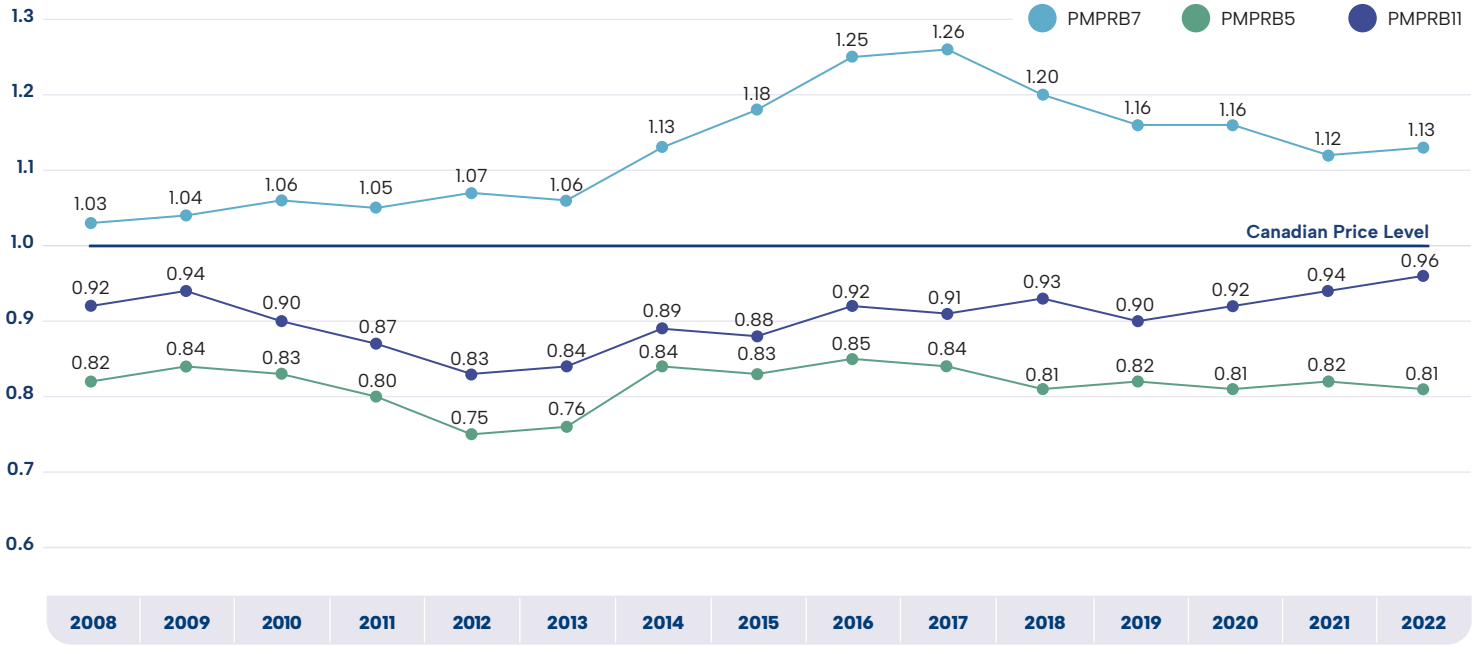
TABLE 8. AVERAGE FOREIGN-TO-CANADIAN PRICE RATIOS, MULTILATERAL COMPARISONS, 2022

	Median	Minimum	Maximum	Mean
Average price ratio at market exchange rates	0.96	0.69	1.34	0.97
Average price ratio at purchasing power parities	1.10	0.70	1.67	1.12
Number of patented medicines	955	955	955	955
Sales ($millions)	$17,713.13	$17,713.13	$17,713.13	$17,713.13

Note: This analysis is based on average transaction prices. For an alternative version based on list prices, see Appendix 3.

Data source: PMPRB

FIGURE 26. AVERAGE RATIO OF MEDIAN INTERNATIONAL PRICE (MIP) TO CANADIAN PRICE, AT MARKET EXCHANGE RATES, PMPRB7, PMPRB5, AND PMPRB11, 2008 TO 2022



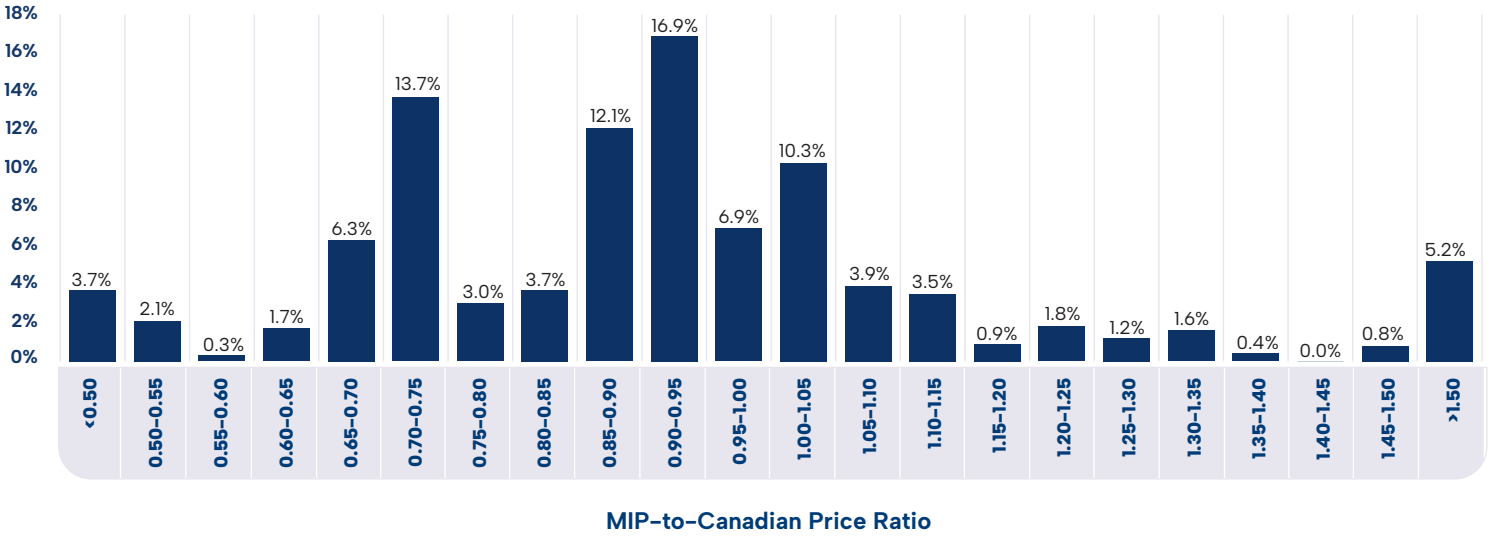
Note: PMPRB7 is France, Germany, Italy, Sweden, Switzerland, the United Kingdom (UK), and the United States (US). PMPRB5 removes Switzerland and the US. PMPRB11 is Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, and the UK. This analysis is based on average transaction prices in Canada. For an alternative version using list prices in Canada, see Appendix 3.

Data source: PMPRB; MIDAS® database, 2008–2022, IQVIA (all rights reserved)

Figure 27 offers more detail on the medicine-level MIP-to-Canadian ratios underlying the averages reported in Table 8. This figure distributes the 2022 sales of each patented medicine according to the value of its MIP-to-Canadian price ratio (more exactly, according to the range into which the ratio fell).[17] These results show a substantial dispersion in medicine-level price ratios: while patented medicines with MIP-to-Canadian price ratios between 0.90 and 1.10 accounted for 38.0% of sales, those with ratios less than 0.90 accounted for 46.6% of sales and medicines with ratios exceeding 1.10 accounted for the remaining 15.4%. Approximately one quarter of the medicines assessed had an MIP-to-Canadian ratio greater than 1.50.

This analysis uses average transaction prices for the Canadian market. A parallel analysis using Canadian list prices is available in Appendix 3.

FIGURE 27. RANGE DISTRIBUTION, SHARE OF SALES BY MIP-TO-CANADIAN PRICE RATIO, 2022



Note: This analysis is based on average transaction prices in Canada. For an alternative version using list prices in Canada, see Appendix 3.
Data source: PMPRB

In 2022, approximately 58% of Canadian patented medicines were priced above the median international level.[18] Table 9 examines the impact of this difference by therapeutic class. Medicines that share the fourth level ATC classification ("ATC4")[19] are grouped to identify distinct chemical/pharmacological/therapeutic subgroups, allowing for a calculation of the average MIP-to-Canadian price ratios among medicines that may be used to treat the same conditions.

Table 9 identifies the top 10 ATC4s in 2022 in which the difference between Canadian and median prices had the largest effect on Canadian patented medicine spending. For example, had Canadian prices been in line with the international median for these classes of medicines in 2022, sales in Canada would have been reduced by approximately $1,559 million (an average reduction of 12% for these ATC4s). Of the 136 DINs classified into these 10 ATC4s, 53% were priced above the median international price.

TABLE 9. TOP 10 ATC4S* BY TOTAL SALES GREATER THAN MEDIAN INTERNATIONAL PRICES, 2022

Description	ATC4*	No. of companies	No. of chemicals in ATC4 (No. currently under patent)	Total patented DINs	Patented DINs greater than median price	2022 net revenues for patented DINs ($millions)	Patented DINs ATC4 share of 2022 revenues	MIP-to-Canadian ratio (min. 5) of patented DINs†	Impact of difference on patented medicines in 2022 ($millions)
Tumor necrosis factor alpha (TNF-α) inhibitors	L04AB	4	5 (3)	13	10	$861.50	4.68%	0.76	$221.87
Other muscle relaxants, peripherally acting agents	M03AX	3	3(3)	8	5	$358.80	1.95%	0.75	$211.42
Combinations of oral blood glucose lowering drugs	A10BD	5	11(6)	24	21	$400.72	2.18%	0.60	$207.08
Antineovascularisation agents	S01LA	4	5(4)	5	4	$743.37	4.04%	0.75	$190.76
Sodium-glucose co-transporter 2 (SGLT2) inhibitors	A10BK	3	4(3)	6	6	$670.00	3.64%	0.74	$178.54
Dipeptidyl peptidase 4 (DPP-4) inhibitors	A10BH	3	4(3)	7	7	$272.61	1.48%	0.52	$135.04
Selective immunosuppressants	L04AA	14	26(18)	30	4	$1,332.00	7.24%	0.94	$124.89
Centrally acting sympathomimetics	N06BA	2	5(3)	26	4	$411.17	2.23%	0.97	$105.49
Other respiratory system products	R07AX	1	5(4)	11	7	$606.14	3.29%	0.93	$93.09
Other drugs affecting bone structure and mineralization	M05BX	2	3(3)	6	4	$135.87	0.74%	0.80	$91.40

* Level 4 of the Anatomical Therapeutic Chemical (ATC) classification system maintained by the World Health Organization.

† For cases where the Canadian average transactional price was below the median international price, the MIP-to-Canadian ratio was set to 1.00.

Data source: PMPRB

ENDNOTES

[14] The number of medicines and sales these ratios encompass vary because it is not always possible to find a matching foreign price for each strength and dosage form of a patented medicine sold in Canada. All bilateral average price ratios reported in Table 7 combined represent at least 64% of 2022 Canadian sales, while the multilateral ratios in Table 8 cover over 96%.

[15] The publicly available ex-factory price includes any price of a patented medicine that is agreed on by the rights holder and the appropriate regulatory authority of the country.

[16] IQVIA's MIDAS® database is the source of sales data used in this analysis. MIDAS® summarizes data obtained from IQVIA's detailed audits of pharmaceutical purchases. MIDAS® contains information on sales of individual medicines, measured in both currency and physical units. It also includes information on medicine manufacturer, active ingredient, brand, form, strength, pack-size, patent status, and therapeutic class. Sales estimates are based directly on the purchase information obtained in its pharmacy audits. To obtain the value of a company's ex-factory sales of a particular medicine, IQVIA removes an estimate of wholesalers' mark-ups from the acquisition costs reported. It should be noted that the acquisition costs used by IQVIA are based on invoiced prices. Off-invoice discounts, free goods, and other forms of price reduction such as rebates are therefore not represented in the MIDAS® data.

[17] To produce the results represented in this figure, foreign prices were converted to their Canadian-dollar equivalents at market exchange rates.

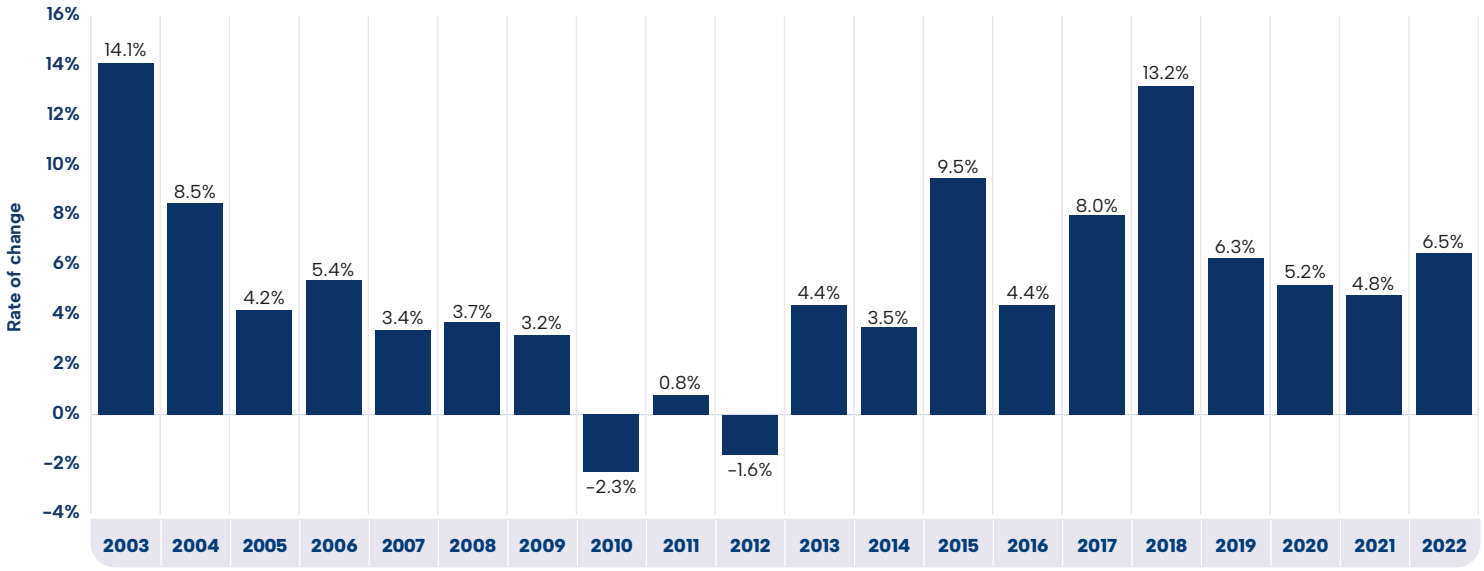
[18] This outcome is not inconsistent with the current Guidelines, which contemplate, post introduction, annual price increases in line with general inflation, as long as prices remain below the highest international price.

[19] ATCs used in this analysis are those maintained under the World Health Organization's Collaborating Centre for Drug Statistics Methodology. The first level of an ATC code describes the anatomical main group and has one letter. The second level divides the main groups into pharmacological/therapeutic groups and has two digits. The third and fourth levels divide these into distinct chemical/therapeutic/pharmacological subgroups and each has one letter. The fifth level defines an individual chemical substance and has two digits. For example, in the case of S01LA (as found in Table 9), "S" indicates that these medicines treat the sensory organs; "01" that they specifically treat ophthalmological indications; "L" that they consist of ocular vascular disorder agents; and "A" that they are specifically antineovascularisation agents. An individual medicine belonging to this group is aflibercept (Eylea), represented by the fifth level ATC S01LA05. For further information, please refer to **http://www.whocc.no/atc_ddd_index/**

UTILIZATION OF PATENTED MEDICINES

The price and sales data used to calculate the PMPI also allow the PMPRB to examine trends in the quantities of patented medicines sold in Canada. The PMPRB maintains the Patented Medicines Quantity Index (PMQI) for this purpose. Figure 28 provides average rates of utilization growth, as measured by the PMQI, from 2003 through 2022.

FIGURE 28. ANNUAL RATE OF CHANGE, PATENTED MEDICINES QUANTITY INDEX (PMQI), 2003 TO 2022



Data source: PMPRB

CANADA IS A TOP 10 GLOBAL MARKET

Canada is an important market for pharmaceuticals representing 2.2% of worldwide sales in 2022.

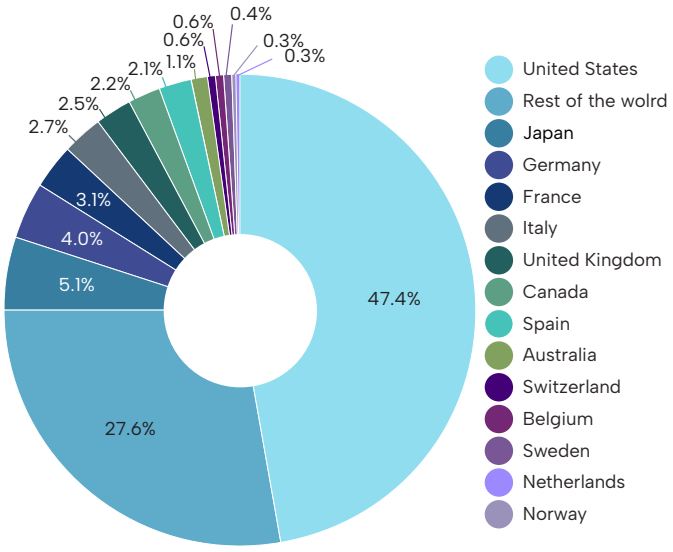
Canada spends nearly the same amount as the UK on pharmaceuticals despite having less than two thirds the population.

CANADIAN MEDICINE EXPENDITURES IN THE GLOBAL CONTEXT

IQVIA[20] regularly reports on medicine sales across a large number of countries. Based on sales data from this source, Figure 29 provides shares of global sales for Canada and other major national markets including the PMPRB11 countries.[21] The Canadian market accounted for 2.2% of the global market in 2022. Canada has been consistently at about 2.0%–2.5% over the last decade.

Figure 30 gives the average annual rate of growth in total medicine sales for Canada and the PMPRB11, individually and collectively. From 2013 to 2022, sales of medicines in Canada rose at an average annual rate of 5.5%. This is slightly above the average rate of growth in medicine sales among the PMPRB11 countries over the same period.

FIGURE 29. DISTRIBUTION OF MEDICINE SALES AMONG MAJOR NATIONAL MARKETS, 2022

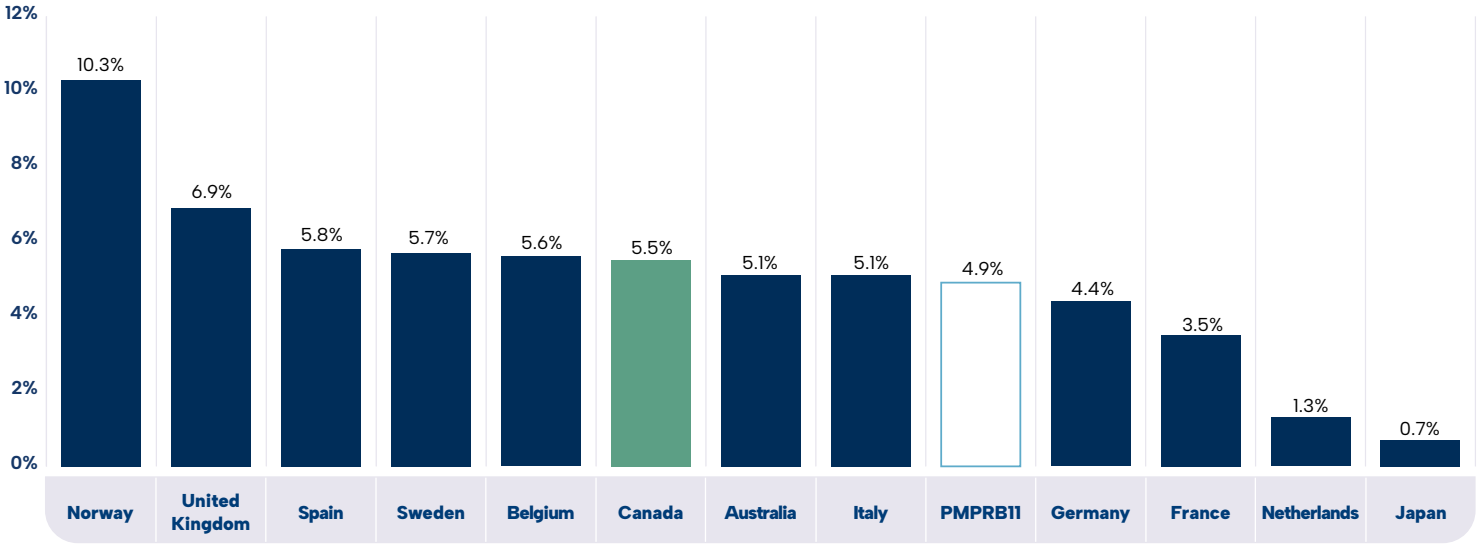


Data source: MIDAS® database, 2022, IQVIA (all rights reserved)

1.9% MEDICINE EXPENDITURES IN CANADA

In 2020, Canadians spent 1.9% of gross domestic product on medicines. This was the second highest share in the PMPRB11, behind only Japan.

FIGURE 30. AVERAGE RATE OF GROWTH OF MEDICINE SALES, AT CONSTANT 2022 MARKET EXCHANGE RATES, BY COUNTRY, CANADA AND THE PMPRB11, 2013 TO 2022

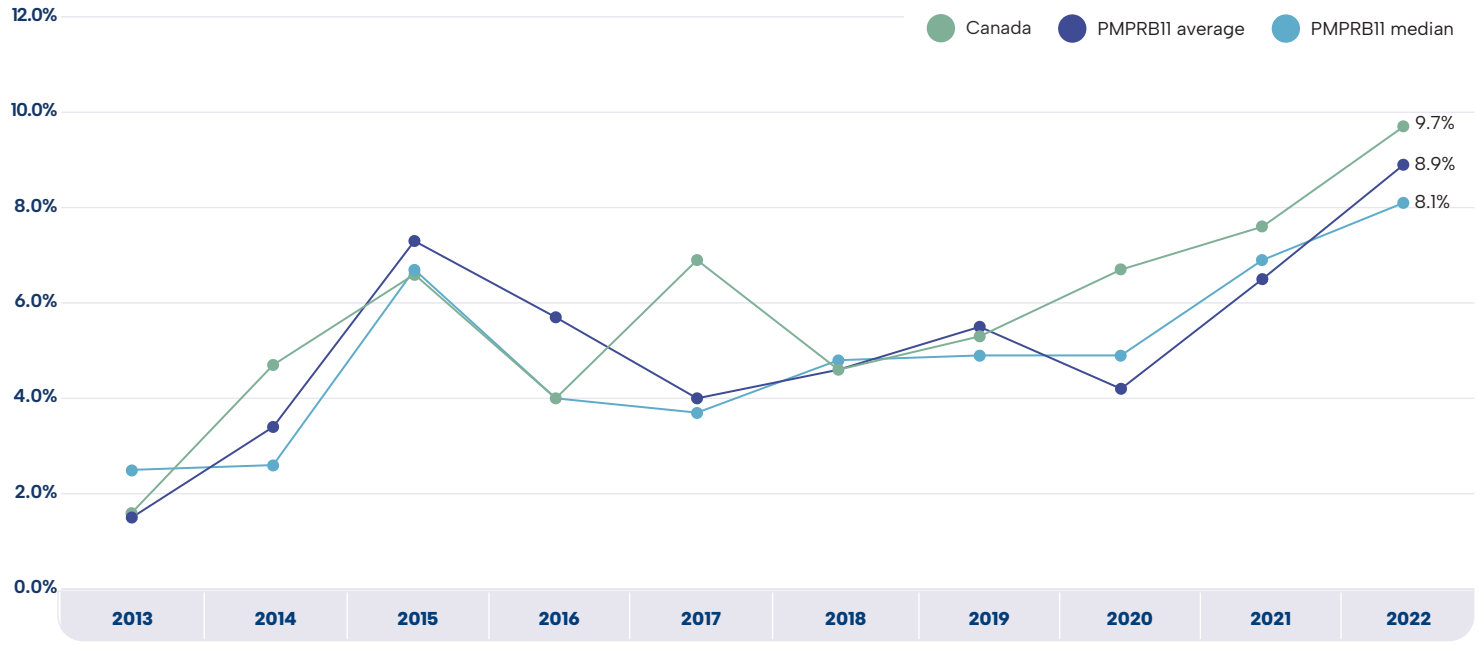


Data source: MIDAS® database, 2013–2022 IQVIA (all rights reserved)

Figure 31 compares rates of year-over-year growth in medicine sales for the entire pharmaceutical market in Canada and the PMPRB11 countries combined. In 2022, sales grew at a slightly faster rate in Canada than in the PMPRB11.

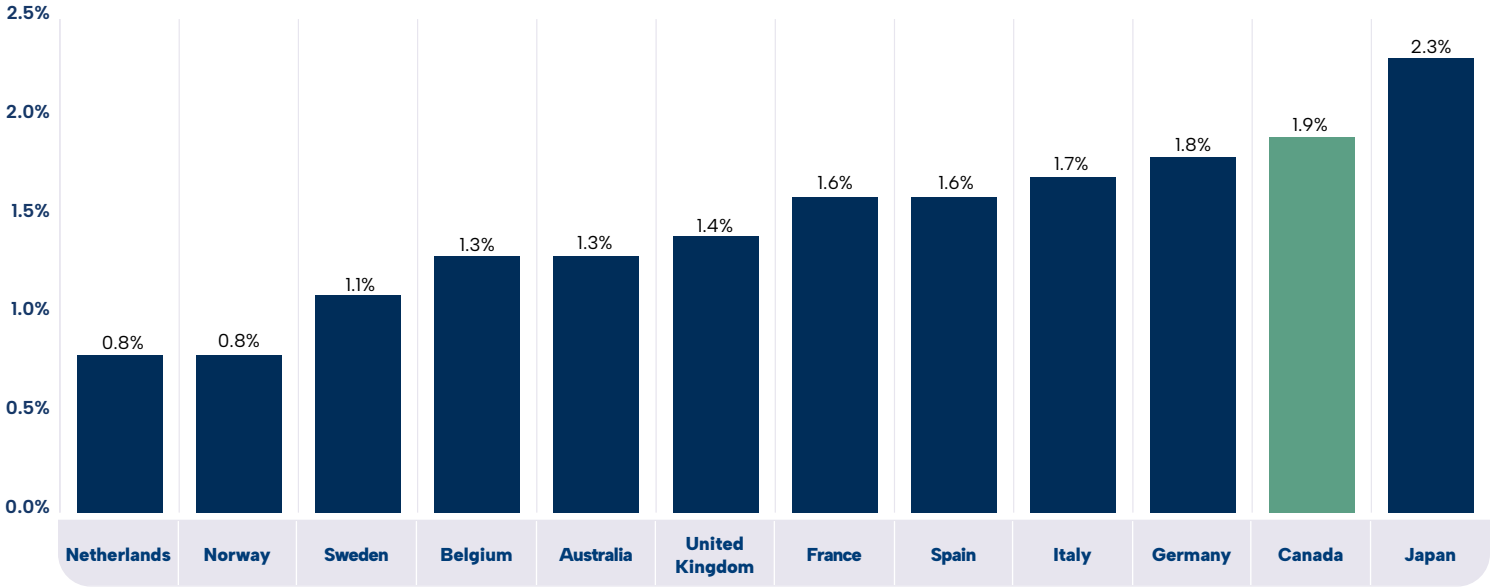
The proportion of national income allocated to the purchase of medicines provides another way to compare medicine costs across countries.[22] Figure 32 gives medicine expenditures as a share of gross domestic product (GDP) for Canada and the PMPRB11 countries based on data for 2020. Medicine expenditures absorbed between 0.8% and 2.3% of the GDP in the PMPRB11. The Canadian value of 1.9% was second only to Japan but just slightly above Germany (1.8%) and Italy (1.7%).

FIGURE 31. AVERAGE ANNUAL RATE OF CHANGE IN MEDICINE SALES, AT CONSTANT 2022 MARKET EXCHANGE RATES, CANADA AND THE PMPRB11, 2013 TO 2022



Data source: MIDAS® database, 2013–2022, IQVIA (all rights reserved)

FIGURE 32. MEDICINE EXPENDITURES AS A SHARE OF GDP, CANADA AND THE PMPRB11, 2020



Data source: OECD

Table 10 provides a historical perspective on the expenditures-to-GDP ratio and per capita spending.[23] Between 2011 and 2020, Canada's ratio was unchanged, and the ratios of three PMPR11 countries—Belgium, France, and the Netherlands—declined. In 2020, Canada had the third-highest spending per capita on medicines compared to the PMPRB11, behind the Japan and Germany.

TABLE 10. MEDICINE EXPENDITURES AS A SHARE OF GDP AND PER CAPITA, CANADA AND THE PMPRB11, 2011 AND 2020

	Share: Medicine Expenditures/GDP 2011	Share: Medicine Expenditures/GDP 2020	Growth: GDP 2011–2020	Medicine spending per capita 2011 ($US PPP)	Medicine spending per capita 2020 ($US PPP)
Canada	1.86%	1.86%	25.6%	$755	$839
Australia	1.29%	1.30%	44.1%	$583	$632
Belgium	1.41%	1.25%	39.3%	$552	$609
France	1.68%	1.62%	32.9%	$623	$726
Germany	1.54%	1.75%	37.5%	$652	$948
Italy	1.63%	1.72%	18.0%	$575	$670
Japan	1.98%	2.30%	13.4%	$707	$954
Netherlands	0.95%	0.78%	34.1%	$427	$427
Norway	1.50%	1.62%	12.2%	$397	$473
Spain	1.50%	1.62%	20.8%	$446	$560
Sweden	1.09%	1.13%	37.9%	$467	$562
United Kingdom	1.25%	1.42%	30.5%	$462	$590

Data source: OECD

Table 11 gives the composition of rights holders' sales by therapeutic class for Canada and the PMPRB11, individually by country and as an aggregate.[24] The results suggest considerable similarity across countries.

TABLE 11. DISTRIBUTION OF MEDICINE SALES BY MAJOR THERAPEUTIC CLASS, CANADA AND THE PMPRB11, 2022

Therapeutic class	Canada	PMPRB11	Australia	Belgium	France	Germany	Italy	Japan	Netherlands	Norway	Spain	Sweden	United Kingdom
A: Alimentary tract and metabolism	14.9%	11.3%	12.1%	9.7%	8.7%	10.8%	10.4%	13.5%	17.0%	12.4%	11.3%	11.2%	11.0%
B: Blood and blood-forming organs	4.4%	7.8%	5.3%	9.6%	8.6%	8.8%	9.0%	6.5%	12.3%	7.4%	6.7%	9.7%	7.8%
C: Cardiovascular system	5.8%	7.0%	4.5%	6.5%	6.4%	6.4%	7.9%	8.9%	11.8%	4.7%	7.1%	4.3%	5.0%
D: Dermatologicals	2.9%	2.3%	5.1%	1.6%	1.8%	3.2%	1.8%	2.3%	1.9%	1.7%	1.8%	2.0%	1.9%
G: Genito-urinary system and sex hormones	3.2%	2.3%	2.9%	2.2%	2.1%	2.0%	2.4%	2.4%	3.2%	3.0%	2.6%	2.7%	2.4%
H: Systemic hormonal preparations	1.1%	1.7%	1.0%	1.3%	1.7%	1.7%	1.5%	2.2%	2.1%	2.4%	1.5%	2.1%	1.4%
J: General anti-infective for systemic use	8.2%	8.9%	7.5%	7.4%	9.2%	8.9%	11.0%	7.3%	7.8%	8.9%	10.3%	10.6%	9.5%
L: Antineoplastics and immunomodulating agents	26.9%	27.4%	23.3%	35.6%	33.2%	26.5%	29.0%	23.1%	3.1%	31.1%	29.6%	27.8%	29.0%
M: Musculo-skeletal system	2.7%	3.4%	3.0%	2.5%	2.3%	3.5%	2.9%	5.4%	2.2%	3.3%	2.6%	3.4%	2.3%
N: Nervous system	15.3%	12.2%	12.9%	11.0%	11.8%	13.5%	12.0%	10.0%	17.0%	13.7%	14.6%	13.3%	12.5%
P: Antiparasitic products	0.1%	0.1%	0.2%	0.1%	0.1%	0.2%	0.0%	0.1%	0.3%	0.2%	0.1%	0.1%	0.1%
R: Respiratory system	6.5%	7.0%	9.6%	7.2%	6.3%	7.5%	6.1%	4.9%	15.2%	6.2%	7.0%	6.1%	10.1%
S: Sensory organs	4.1%	3.1%	4.5%	2.2%	3.3%	2.8%	1.8%	3.5%	4.2%	2.0%	2.7%	3.7%	4.2%
V: Various	3.8%	5.3%	8.2%	3.3%	4.5%	4.3%	4.3%	9.9%	1.9%	2.9%	2.1 %	2.9%	2.9%
All therapeutic classes*	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**

* Values may not add to 100% due to rounding.

Data source: MIDAS® database, 2022, IQVIA (all rights reserved)

ENDNOTES

20 Most of the statistical results presented in this section are based on sales data from the MIDAS® database, 2005-2022, IQVIA (all rights reserved). MIDAS® data covers the pharmacy and hospital sectors.

21 The results given in Figures 30 through 32 and Table 11 are based on estimates of ex-factory sales revenues encompassing all prescription medicines, including patented and non-patented branded medicines, and patented and non-patented generic medicines. These estimates have been converted to Canadian dollar equivalents at annual average market exchange rates. Fluctuations in these rates can substantially influence these shares.

22 Comparisons made on this basis will reflect international differences in prices, overall utilization, and patterns of therapeutic choice, as well as differences in national income.

23 To make use of the best and most up-to-date data on OECD medicine expenditures, the GDP in Table 10 was calculated using the purchasing power parity (PPP). PPPs are corrected for the relative cost of living based on a standard basket of goods, therefore, the GDP growth rates reported in Table 10 will be different than those generated using other methodologies. Details on purchasing power parity are provided in the text associated with Table 7.

24 Note that the data used to produce Table 11 encompasses patented and non-patented brand-name medicines and patented and non-patented generic medicines. Hence, the results reported for Canada are not directly comparable to the results reported in Figure 15, which include only patented medicines.

418 PUBLIC

NATIONAL PRESCRIPTION DRUG UTILIZATION INFORMATION SYSTEM:

SUPPORTING HEALTH CARE DECISION MAKING IN CANADA

How medications are used—where, by whom, and for what—has an impact on the amount that we spend on medicines. The PMPRB contributes to Canada's understanding of medicine usage through the National Prescription Drug Utilization Information System (NPDUIS) initiative, generating comprehensive, accurate information to help guide decision making and support the sustainability of our pharmaceutical system.

BACKGROUND

NPDUIS is a research initiative established by federal, provincial, and territorial Ministers of Health in September 2001. It is a partnership between the PMPRB and the Canadian Institute for Health Information (CIHI).

At the request of the Minister of Health pursuant to section 90 of the *Patent Act*, the PMPRB has the mandate to conduct analysis that provides decision makers with critical information and intelligence on price, utilization, and cost trends so that Canada's healthcare system has more comprehensive and accurate information on how medicines are being used and on sources of cost pressures.

The specific research priorities and methodologies for NPDUIS are established with the guidance of the NPDUIS Advisory Committee and reflect the priorities of the participating jurisdictions. The Advisory Committee is composed of representatives from public drug plans in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon, the Non-Insured Health Benefits (NIHB) Program, and Health Canada. It also includes observers from the CIHI, the Canadian Agency for Drugs and Technologies in Health (CADTH), the Ministère de la Santé et des Services sociaux du Québec (MSSS), and the pan-Canadian Pharmaceutical Alliance (pCPA) Office.

NPDUIS operates independently of the price review activities of the PMPRB. NPDUIS reports do not contain information that is confidential or privileged under sections 87 and 88 of the *Patent Act*.

HIGHLIGHTS

Since the start of 2022, the PMPRB has published six analytical reports, one chartbook, and eight posters under the NPDUIS banner.

ANNUAL PUBLICATIONS AND REPORT SERIES

- ***Formularies in Canada – Part 3: Medicines Assessed by the Common Drug Review*** (February 2022)
- ***Meds Pipeline Monitor, 2021*** (April 2022)
- ***Meds Entry Watch, 6th Edition*** (April 2022)
- ***Drug Shortages in Canada and their Impact on Public Drug Plans, 2017/18 to 2019/20*** (September 2022)
- ***CompassRx: Annual Public Drug Plan Expenditure Report, 8th Edition, 2020/21*** (January 2023)
- ***Market Intelligence Report: Antidiabetic Drugs, 2012–2021*** (May 2023)

CHARTBOOK

- ***Expensive Drugs for Rare Diseases: Canadian Trends and International Comparisons, 2011–2020*** (January 2022)

POSTER PRESENTATIONS

- **Drug Shortages in Canada and their Impact on Public Drug Plans, 2017/18 to 2019/20**
- **The COVID-19 Pipeline: Vaccines and Treatments on the Horizon**
- **Alignment between the estimated therapeutic value of medicines and their Canadian prices**
- **The missing claimants of 2020: Who went without claims in Canada during the first year of the COVID-19 pandemic and what does it mean for public and private insurers?**
- **The COVID-19 Pipeline: Vaccines and Treatments on the Horizon**
- **Insight into approvals, marketing, and pricing of new medicines in Canadian and international markets**
- **The Cost of Drug Shortages for Canadian Insurers**
- **Canada's Evolving Market for Biosimilars and What It Means for Payers**

The PMPRB continues to support and strengthen its NPDUIS engagement activities by regularly consulting with the NPDUIS Advisory Committee, participating in conferences and stakeholder committees, and organizing bilingual information sessions with interested stakeholders to share the results of the analytical studies.

RESEARCH AGENDA

The NPDUIS research agenda for the 2023–24 fiscal year includes plans to publish the following analytical studies:

ANNUAL PUBLICATIONS AND REPORT SERIES

- *CompassRx: 9th Edition, 2021/22*
- *Meds Pipeline Monitor, 2022*
- *Meds Entry Watch, 7th Edition*
- *Meds Entry Watch, 8th Edition*
- *Market Intelligence Report: Medicines for Heart Failure*

Additional research topics may be pursued based on consultation with the NPDUIS Advisory Committee.

420 PUBLIC

ANALYSIS OF RESEARCH AND DEVELOPMENT EXPENDITURES:

TRACKING REPORTED R&D SPENDING IN CANADA

Pharmaceutical research and development (R&D) is an important piece in advancing innovation in global and national health care. In Canada, the ratio of R&D expenditures to sales revenues for pharmaceutical rights holders has been steadily decreasing since the late 1990s. In 2022, it was at 3.1% for all rights holders and 3.2% for members of Innovative Medicines Canada.

ANALYSIS OF RESEARCH AND DEVELOPMENT EXPENDITURES

The Act mandates the PMPRB to monitor and report on pharmaceutical R&D spending. This section provides key statistics on the current state of pharmaceutical R&D investment in Canada.

DEFINITION OF R&D EXPENDITURES

Pursuant to section 6 of the Regulations, rights holders are required to report R&D expenditures that would have qualified for a Scientific Research and Experimental Development (SR&ED) investment tax credit under the provisions of the *Income Tax Act* that came into effect on December 1, 1987.[25] By this definition, R&D expenditures may include current expenditures, capital equipment costs, and allowable depreciation expenses. Market research; sales promotions; quality control or routine testing of materials, devices, or products; and routine data collection are not eligible for an investment tax credit, and, therefore, are not to be included in the R&D expenditures reported by rights holders.

DATA SOURCES

The statistical results in this section were entirely derived from data submitted to the PMPRB by rights holders.

The Act requires each rights holder to report its total gross revenues from sales of all medicines for human or veterinary use (including revenues from sales of non-patented medicines and from licensing agreements) and R&D expenditures in Canada related to medicines (both patented and non-patented for human or veterinary use).

Rights holders submit this information to the PMPRB by means of its Form 3 (Revenues and Research and Development Expenditures Provided Pursuant to subsection 88(1) of the *Patent Act*).

The *Patented Medicines Regulations* (Regulations) require that each submitted Form 3 be accompanied by a certificate stating the information it contains is "true and correct". The Board does not audit Form 3 submissions, but it does review submitted data for anomalies and inconsistencies, seeking corrections or clarifications from rights holders where necessary. To confirm

3.1% R&D-TO-SALES RATIO

The R&D-to-sales ratio for all rights holders was 3.1% in 2022.

This represents a 74% decrease from a peak of 11.7% in 1995.

that PMPRB staff has correctly interpreted the data submitted, each rights holder is given the opportunity to review and confirm the accuracy of its own R&D-to-sales ratio before that ratio is published.

FAILURE TO FILE (FORM 3)

It is a rights holder's responsibility to ensure a complete and accurate Form 3 is filed within the time frame set out in the Regulations. If a rights holder fails to meet these filing requirements, the Board may issue an Order demanding compliance. No such Board Orders were issued for the 2022 reporting period.

COVERAGE

Note that companies without sales of patented medicines do not need to report their R&D expenditures to the PMPRB. This has two implications:

First, the statistical results reported herein should not be understood as representative of all pharmaceutical research conducted in Canada. For example, a company may sell only non-patented medicines but still perform considerable research. Similarly, a company may conduct research and have no medicine sales at all.[26] The results presented below will not reflect the R&D expenditures of firms in either scenario.

Second, as new patented medicines enter the Canadian market and existing relevant patents expire, the number and identity of companies required to file R&D data may change from year to year. In 2022, 100 companies reported on their R&D activity. Of these, 37 were members of Innovative Medicines Canada.

DEFINITION OF SALES REVENUES

For reporting purposes, sales revenues are defined as total gross revenues from sales in Canada of all medicines and from licensing agreements (e.g., royalties and fees accruing to the rights holder related to sales in Canada by licensees).

TOTAL SALES REVENUES AND R&D EXPENDITURES

Table 12 provides an overview of reported sales revenues and R&D expenditures from 1988 to 2022.

Rights holders reported total 2022 sales revenues of $29.1 billion, an increase of 6.1% from 2021. Sales revenues reported by Innovative Medicines Canada members were $23.3 billion, accounting for 80% of the total. Less than 1% of reported sales revenues were generated by licensing agreements. Rights holders reported R&D expenditures of $914.0 million in 2022, a decrease of 1.0% from 2021. Innovative Medicines Canada members reported R&D expenditures of $748.6 million in 2022, an increase of 1.7% over the previous year. Innovative Medicines Canada members accounted for 82.0% of all reported R&D expenditures in 2022.

R&D-TO-SALES RATIOS

Table 12 and Figure 33 also provide ratios of R&D expenditures to sales revenues. It should be noted that with the adoption of the 1987 amendments to the Act, Innovative Medicines Canada made a public commitment to increase its members' annual R&D expenditures to 10% of sales revenues by 1996.[27] This level of R&D expenditure was reached by 1993, with the ratio exceeding 10% in some years.

The ratio of R&D expenditures to sales revenues among all rights holders was 3.1% in 2022, a decrease from 2021 and the lowest level yet recorded. The overall R&D-to-sales ratio has been less than 10% for the past 22 years.

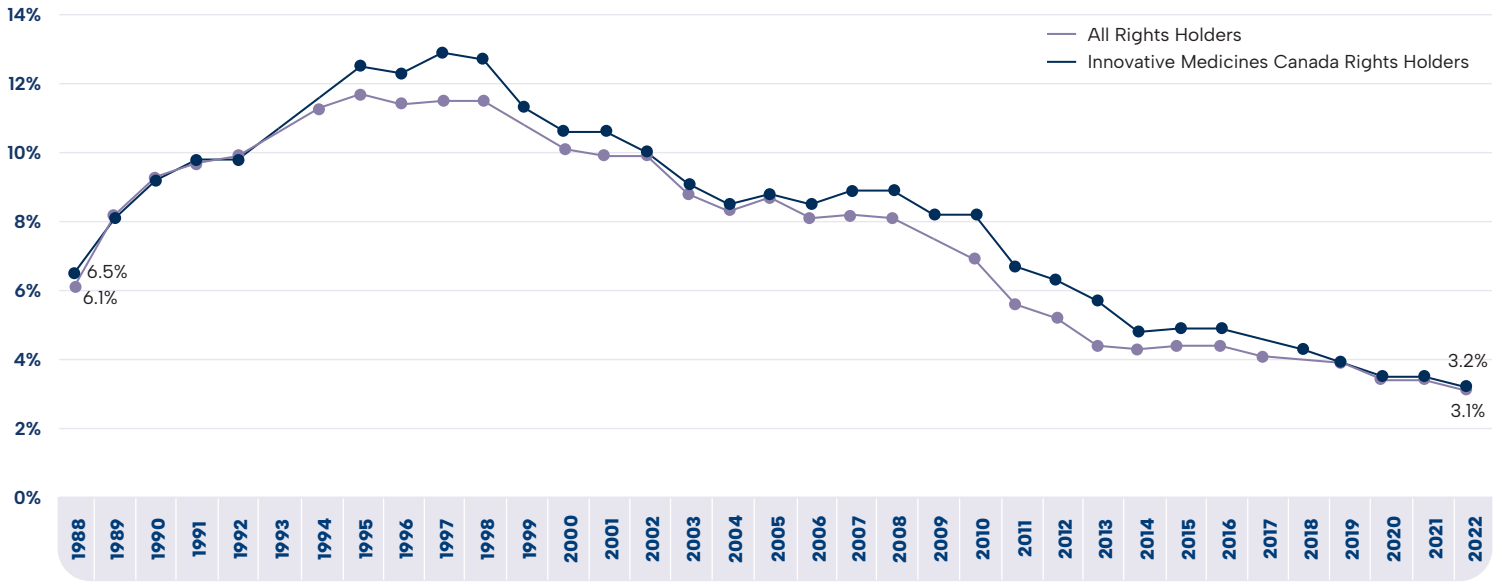
The corresponding R&D-to-sales ratio for members of Innovative Medicines Canada was 3.2%, also a decrease from 2021.[28] The Innovative Medicines Canada ratio has been less than 10% for the past 20 years. Table 20 in Appendix 4 provides details on the range of 2022 R&D-to-sales ratios. Of the 100 companies reporting in 2022, 84.0% had R&D-to-sales ratios below 10.0%.

TABLE 12. TOTAL R&D EXPENDITURES AND R&D-TO-SALES RATIOS OF REPORTING COMPANIES, 1988 TO 2022

Year	All rights holders					Innovative Medicines Canada rights holders				R&D-to-sales ratio: all rights holders	R&D-to-sales ratio: Innovative Medicines Canada rights holders
	Number of companies reporting	R&D expenditures by all rights holders ($millions)	Change from previous year	Sales revenues ($millions)	Change from previous year	R&D expenditures by Innovative Medicines Canada rights holders ($millions)	Change from previous year	Sales revenues ($millions)	Change from previous year		
2022	100	$914.0	-1.0%	$29,144.9	6.1%	$748.6	1.7%	$23,342.9	9.9%	3.1%	3.2%
2021	100	$922.9	12.2%	$27,478.5	13.2%	$735.9	11.0%	$21,243.9	12.4%	3.4%	3.5%
2020	99	$822.9	-7.9%	$24,278.2	5.1%	$662.8	1.6%	$18,902.9	12.1%	3.4%	3.5%
2019	101	$893.2	0.1%	$23,101.0	1.9%	$652.6	-9.7%	$16,858.8	0.4%	3.9%	3.9%
2018	93	$892.6	2.4%	$22,663.4	7.2%	$723.0	-4.3%	$16,789.7	2.7%	4.0%	4.3%
2017	85	$871.4	-5.1%	$21,147.2	1.4%	$755.8	-1.8%	$16,349.8	4.8%	4.1%	4.6%
2016	78	$918.2	5.7%	$20,855.7	5.9%	$769.9	0.3%	$15,599.9	0.2%	4.4%	4.9%
2015	77	$869.1	9.7%	$19,693.3	6.7%	$767.4	7.8%	$15,565.1	4.7%	4.4%	4.9%
2014	75	$792.2	-0.8%	$18,455.1	1.0%	$711.7	2.0%	$14,861.1	9.2%	4.3%	4.8%
2013	81	$798.3	-14.7%	$18,268.1	1.4%	$697.5	-15.4%	$13,614.8	3.4%	4.4%	5.1%
2012	85	$936.1	-5.6%	$18,021.1	1.3%	$824.1	-8.6%	$13,162.8	-2.1%	5.2%	6.3%
2011	79	$991.7	-15.8%	$17,798.8	4.7%	$901.2	-9.9%	$13,446.1	10.7%	5.6%	6.7%
2010	82	$1,178.2	-7.4%	$17,000.0	-0.3%	$1,000.2	-11.7%	$12,149.0	-11.8%	6.9%	8.2%
2009	81	$1,272.0	-2.9%	$17,051.9	4.5%	$1,132.9	-3.4%	$13,780.0	4.6%	7.5%	8.2%
2008	82	$1,310.7	-1.1%	$16,316.7	2.0%	$1,172.2	-1.0%	$13,178.2	-1.4%	8.1%	8.9%
2007	82	$1,325.0	9.5%	$15,991.0	7.3%	$1,184.4	24.8%	$13,359.8	20.0%	8.3%	8.9%
2006	72	$1,210.0	-1.9%	$14,902.0	4.7%	$949.0	-8.8%	$11,131.2	-5.8%	8.1%	8.5%
2005	80	$1,234.3	5.5%	$14,231.3	0.5%	$1,040.1	3.9%	$11,821.4	0.0%	8.7%	8.8%
2004	84	$1,170.0	-2.0%	$14,168.3	4.0%	$1,000.8	0.8%	$11,819.0	8.8%	8.3%	8.5%
2003	83	$1,194.3	-0.4%	$13,631.1	12.8%	$992.9	-3.6%	$10,865.7	5.2%	8.8%	9.1%
2002	79	$1,198.7	13.0%	$12,081.2	12.5%	$1,029.6	10.1%	$10,323.8	16.8%	9.9%	10.0%
2001	74	$1,060.1	12.6%	$10,732.1	15.3%	$935.2	14.7%	$8,835.4	14.3%	9.9%	10.6%
2000	79	$941.8	5.3%	$9,309.6	12.0%	$815.5	4.0%	$7,728.8	11.6%	10.1%	10.6%
1999	78	$894.6	12.0%	$8,315.5	19.2%	$784.3	9.9%	$6,923.4	22.8%	10.8%	11.3%
1998	74	$798.9	10.2%	$6,975.2	10.9%	$713.7	8.6%	$5,640.2	10.6%	11.5%	12.7%
1997	75	$725.1	9.0%	$6,288.4	7.4%	$657.4	10.3%	$5,098.2	4.9%	11.5%	12.9%
1996	72	$665.3	6.4%	$5,857.4	9.9%	$595.8	6.5%	$4,859.5	8.7%	11.4%	12.3%
1995	71	$625.5	11.5%	$5,330.2	7.5%	$559.5	9.8%	$4,468.8	1.4%	11.7%	12.5%
1994	73	$561.1	11.4%	$4,957.4	4.4%	$509.5	10.4%	$4,407.2	2.0%	11.3%	11.6%
1993	70	$503.5	22.1%	$4,747.6	14.0%	$461.4	24.0%	$4,321.4	14.4%	10.6%	10.7%
1992	71	$412.4	9.6%	$4,164.4	6.9%	$372.1	9.0%	$3,778.4	6.5%	9.9%	9.8%
1991	65	$376.4	23.2%	$3,894.8	18.1%	$341.4	24.7%	$3,546.9	19.5%	9.7%	9.6%
1990	65	$305.5	24.8%	$3,298.8	11.0%	$273.8	25.8%	$2,967.9	10.5%	9.3%	9.2%
1989	66	$244.8	47.4%	$2,973.0	9.4%	$217.6	34.7%	$2,685.5	7.3%	8.2%	8.1%
1988	66	$165.7	—	$2,718.0	—	$161.5	—	$2,502.3	—	6.1%	6.5%

Data source: PMPRB

FIGURE 33. R&D-TO-SALES RATIO, PHARMACEUTICAL RIGHTS HOLDERS, 1988 TO 2022



Data source: PMPRB

CURRENT R&D EXPENDITURES BY TYPE OF RESEARCH

Table 13 and Figure 34 (as well as Figure 40 in Appendix 4) provide information on the allocation of 2022 R&D expenditures[29] in basic and applied research as well as other qualifying R&D.[30] Rights holders reported spending $132.0 million on basic research in 2022, representing 14.9% of current R&D expenditures, an increase of 17.1% over the previous year. A reported $484.4 million was spent on applied research, representing 54.9% of current R&D expenditures. Clinical trials (Phase I to III) accounted for 80.0% of applied research expenditures.

TABLE 13. CURRENT R&D EXPENDITURES BY TYPE OF RESEARCH, 2022 AND 2021

Type of research	Expenditures: 2022 ($millions)	Share: 2022	Expenditures: 2021 ($millions)	Share: 2021	Annual change in expenditures
Basic	**$132.0**	**14.9%**	**$112.7**	**12.6%**	**17.1%**
Chemical	$89.1	10.0%	$70.6	7.9%	26.2%
Biological	$42.9	4.9%	$42.1	4.7%	1.9%
Applied	**$484.4**	**54.9%**	**$507.7**	**56.9%**	**-4.6%**
Manufacturing process	$38.1	4.3%	$44.3	5.0%	-14.0%
Pre-clinical trial I	$39.5	4.5%	$31.6	3.5%	25.0%
Pre-clinical trial II	$19.3	2.2%	$19.7	2.2%	-2.0%
Clinical trial Phase I	$45.2	5.1%	$53.1	5.9%	-14.9%
Clinical trial Phase II	$70.3	8.0%	$78.3	8.8%	-10.2%
Clinical trial Phase III	$272.0	30.8%	$280.7	31.5%	-3.1%
Other qualifying R&D	**$266.4**	**30.2%**	**$272.1**	**30.5%**	**-2.1%**
Total*	**$882.8**	**100%**	**$892.5**	**100%**	**-1.1%**

* Values may not add to totals due to rounding.

Data source: PMPRB

FIGURE 34. CURRENT R&D EXPENDITURES BY TYPE OF RESEARCH, 1988 TO 2022

Data source: PMPRB

CURRENT R&D EXPENDITURES BY PERFORMER

Rights holders report expenditures on research they conduct themselves (intramural) and research performed by other establishments, such as universities, hospitals, and other manufacturers (extramural).

Table 14 shows that 50.6% of 2022 current research expenditures were intramural. Research performed by other companies on behalf of rights holders made up 23.1% of current expenditures, while research conducted in universities and hospitals accounted for 14.5%.

TABLE 14. CURRENT R&D EXPENDITURES BY R&D PERFORMER, 2022 AND 2021

R&D performer	Expenditures: 2022 ($millions)	Share: 2022	Expenditures: 2021 ($millions)	Share: 2021	Annual change in expenditures
Intramural					
Rights holders	$446.6	50.6%	$417.3	46.8%	7.0%
Extramural					
Universities and hospitals	$128.4	14.5%	$147.9	16.6%	-13.2%
Other companies	$203.8	23.1%	$225.9	25.3%	-9.7%
Others	$104.0	11.8%	$101.4	11.4%	2.5%
Total*	**$882.8**	**100%**	**$892.5**	**100%**	**-1.1%**

* Values may not add to totals due to rounding.
Data source: PMPRB

CURRENT R&D EXPENDITURES BY REGION

Table 15 (as well as Tables 21 and 22 in Appendix 4) shows current R&D expenditures by region. As in previous years, current expenditures were heavily concentrated in Ontario and Quebec in 2022, with these provinces accounting for 77.4% of total expenditures.

Between 2021 and 2022, R&D expenditures increased at a year-over-year rate of 1.3% in the Atlantic provinces, 11.9% in Quebec, and 4.9% in Western Canada, and decreased at a rate of 10.0% in Ontario.

TABLE 15. CURRENT R&D EXPENDITURES BY REGION, 2022 AND 2021

Region	Expenditures: 2022 ($millions)	Share: 2022	Expenditures: 2021 ($millions)	Share: 2021	Annual change in expenditures
Atlantic provinces	$13.2	1.5%	$13.0	1.5%	1.3%
Quebec	$262.9	29.8%	$235.0	26.3%	11.9%
Ontario	$419.9	47.6%	$466.4	52.3%	-10.0%
Western provinces	$186.7	21.1%	$178.0	19.9%	4.9%
Territories	$0.1	0.0%	$0.1	0.0%	-0.3%
Total*	**$882.8**	**100%**	**$892.5**	**100%**	**-1.1%**

* Values may not add to totals due to rounding.
Data source: PMPRB

TOTAL R&D EXPENDITURES BY SOURCE OF FUNDS

Table 16 provides information on the sources of funds used by rights holders to finance their R&D activity. Internal company funds remained by far the single largest source of funding in 2022, accounting for 90.6% of total expenditures.

Funds received from government amounted to 0.6% of total expenditures.

TABLE 16. TOTAL R&D EXPENDITURES BY SOURCE OF FUNDS, 2022 AND 2021

Source of funds	Expenditures: 2022 ($millions)	Share: 2022	Expenditures: 2021 ($millions)	Share: 2021	Annual change in expenditures
Company funds	$827.9	90.6%	$832.3	90.2%	-0.5%
Federal/provincial governments	$5.0	0.6%	$5.0	0.5%	1.1%
Others	$81.0	8.9%	$85.7	9.3%	-5.4%
Total*	**$914.0**	**100%**	**$922.9**	**100%**	**-1.0%**

* Values may not add to totals due to rounding.
Data source: PMPRB

THE GLOBAL CONTEXT

Figure 35 compares Canadian pharmaceutical R&D-to-sales ratios to those of the PMPRB11 in 2000, 2010, and 2020. These three years of data provide a snapshot of observed market trends over the past 20 years.

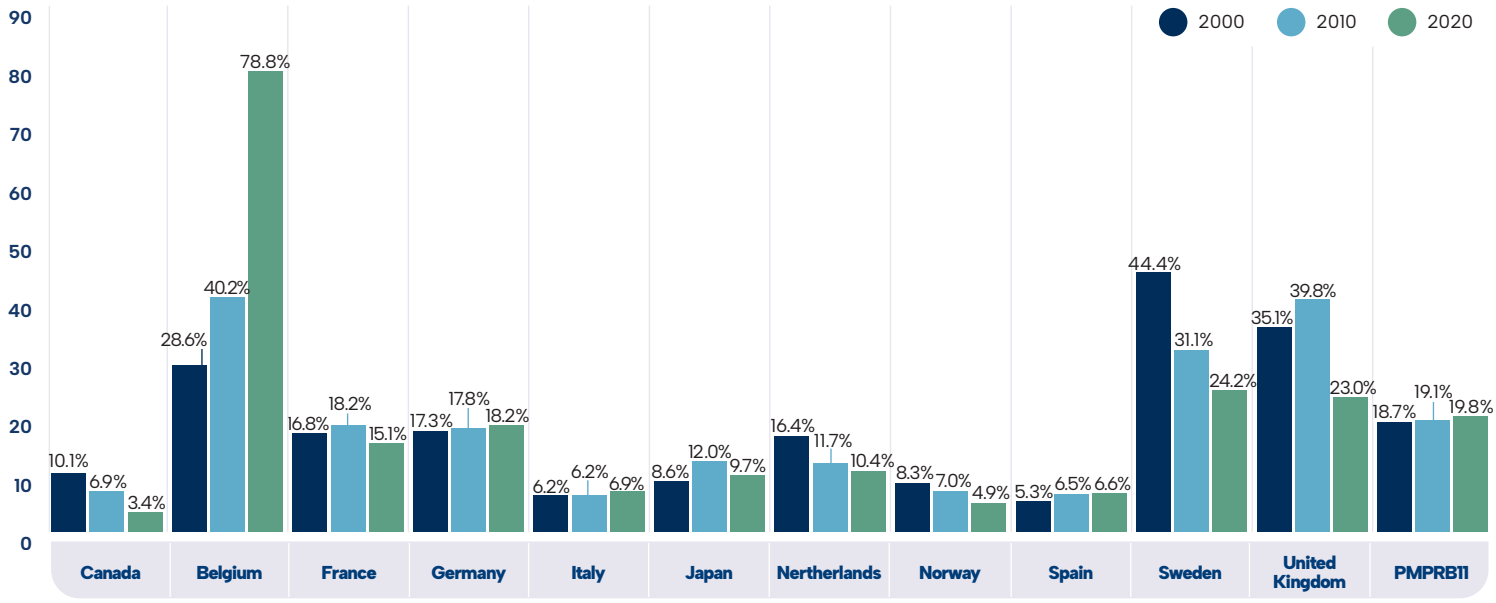
Starting in 2000, Canada had an R&D-to-sales ratio of 10.1%, lower than most PMPRB11 countries. Canada's R&D-to-sales ratio moved down to 6.9% in 2010, below all PMPRB11 countries except for Italy at 6.2% and Spain at 6.5%. In 2020, Canada's R&D-to-sales ratio dropped below that in Spain, becoming the lowest among all comparator countries at 3.4%.

The ratio obtained by aggregating R&D spending and sales across all PMPRB11 countries in 2020 was 19.8%, more than five times that in Canada. The R&D-to-sales ratios represented in Figure 35 may be compared to the average bilateral price ratios reported in Table 7 (see "Comparison of Canadian Prices to Foreign Prices").

A number of comparator countries with patented medicine prices that are, on average, lower than prices in Canada, have achieved much higher R&D-to-sales ratios.

There are a multitude of factors that drive the location of pharmaceutical R&D, including where companies can find the best science base at a reasonable cost and have ready access to a quality clinical trials infrastructure. Although price levels and intellectual property protection are often cited as an important policy lever for attracting R&D, the data has not supported this link domestically or internationally.

FIGURE 35. R&D-TO-SALES RATIO, CANADA AND THE PMPRB11, 2000, 2010, AND 2020



Note: R&D data for Australia was not publicly available.
Data source: PMPRB; European Federation of Pharmaceutical Industries and Associations (EFPIA): *The Pharmaceutical Industry in Figures 2022*; JPMA

ENDNOTES

25 Changes have been made to the Scientific Research and Experimental Development (SR&ED) tax credit since its implementation, including new restrictions on deductions, while other measures have been introduced at the federal level to support innovation and R&D. As per the Regulations, the PMPRB defines R&D based on the 1987 SR&ED definition.

26 This is likely the situation for much of Canada's biotechnology sector. Note, however, that if a rights holder commissions research from another company specializing in biotechnology research, the rights holder should normally include this among the research expenditures that it reports to the PMPRB.

27 As published in the Regulatory Impact Assessment Statement (RIAS) of the Patented Medicines Regulations, 1988, published in the Canada Gazette, Part II, Vol. 122, No. 20 – SOR/DORS/88-474.

28 The R&D-to-sales ratios presented in Table 12 include research expenditures funded by government grants. When the government-funded component is excluded, the ratios for all rights holders and for the members of Innovative Medicines Canada in 2022 remain at 3.1% and 3.2%, respectively.

29 Current R&D expenditures consist of non-capital expenses directly related to research, including (a) wages and salaries; (b) direct material; (c) contractors and sub-contractors; (d) other direct costs such as factory overhead; (e) payments to designated institutions; (f) payments to granting councils; and (g) payments to other organizations. These elements are described in more detail in Form 3 (Revenues and Research and Development Expenditures) available on the **PMPRB website**. Current R&D expenditures accounted for 96.6% of total R&D expenditure in 2022, while capital equipment costs and allowable depreciation expenses made up 1.4% and 2.0%, respectively.

30 "Basic research" is defined as work that advances scientific knowledge without a specific application in mind. "Applied research" is directed toward a specific practical application, comprising research intended to improve manufacturing processes, pre-clinical trials, and clinical trials. "Other qualifying research" includes regulatory submissions, bioavailability studies, and Phase IV clinical trials.

THE PMPRB11 AVERAGE R&D RATIO IS MORE THAN 5X GREATER THAN IN CANADA.

The R&D-to-sales ratio obtained by aggregating R&D spending and sales across all 11 comparator countries in 2020 was 19.8%, compared to just 3.4% in Canada.

APPENDIX 1:
GLOSSARY

These definitions are provided for general assistance only; they have no legal force and should be read in conjunction with the applicable legislation.

Active Ingredient or Medicinal Ingredient: Chemical or biological substance responsible for the claimed pharmacologic effect of a medicine.

ATC: Anatomical Therapeutic Chemical (ATC) classification system, developed and maintained by the World Health Organization (WHO) Collaborating Centre for Drug Statistics Methodology, which divides medicines into different groups according to their site of action and therapeutic and chemical characteristics. This system is used by the PMPRB as a guide for selecting comparable medicines for purposes of price review under the Guidelines.

Drug Identification Number (DIN): A registration number (drug identification number) that the Health Products and Food Branch of Health Canada assigns to each prescription and non-prescription drug product marketed under the *Food and Drug Regulations*. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength of active ingredient(s); pharmaceutical dosage form; route of administration. Different strengths and dosage forms of a medicine may be assigned different DINs.

Drug Product: A particular presentation of a medicine characterized by its pharmaceutical dosage form and the strength of the active ingredient(s) (see "Medicine" below).

Failure to File: The complete or partial failure of a rights holder to comply with regulatory filing requirements pursuant to the *Patent Act* and the *Patented Medicines Regulations*.

Failure to Report: The complete failure of a rights holder to have reported a patented medicine being sold in accordance with regulatory filing requirements pursuant to the *Patent Act* and the *Patented Medicines Regulations*.

License, Voluntary: A contractual agreement between a patent holder and a licensee under which the licensee is entitled to enjoy the benefit of the patent or to exercise any rights in relation to the patent for some consideration (e.g., royalties in the form of a share of the licensee's sales).

Medicine: A medicinal ingredient and/or a substance or a mixture of substances manufactured, sold, or represented for use in the diagnosis, treatment, mitigation, or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; or restoring, correcting, or modifying organic functions in human beings or animals.

Notice of Compliance (NOC): A notice issued under section C.08.004 or C.08.004.01 of the *Food and Drug Regulations*. The issuance of an NOC indicates that a drug product meets the required Health Canada standards for use in humans or animals and that the manufacturer of the product is authorized to market the product in Canada.

Patent: An instrument issued by the Commissioner of Patents in the form of letters patent for an invention.

Patented Medicine Price Index (PMPI): The PMPI was developed by the PMPRB as a measure of average year-over-year change in the transaction prices of patented medicines sold in Canada, based on the price and sales information reported by rights holders.

Patentee: As defined by subsection 79(1) of the *Patent Act,* "the person for the time being entitled to the benefit of the patent for that invention and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a license continued by subsection 11(1) of the *Patent Act Amendment Act*, 1992, that other person in respect of those rights".

PMPRB7: France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States.

PMPRB11: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom.

Research and Development (R&D): Basic or applied research for the purpose of creating new, or improving existing, materials, devices, products, or processes (e.g., manufacturing processes).

Research and Development—Applied Research: R&D directed toward a specific practical application, comprising research intended to improve manufacturing processes, pre-clinical trials, and clinical trials.

Research and Development—Basic Research: R&D defined as work that advances scientific knowledge without a specific application in mind.

Research and Development—Other Qualifying: Eligible research and development expenditures that cannot be classified into any of the preceding categories of "type of research and development". It includes regulatory submissions, bioavailability studies, and Phase IV clinical trials.

Research and Development Expenditures: For the purposes of the *Patented Medicines Regulations*, in particular Sections 5 and 6, research and development includes activities for which expenditures would have qualified for the investment tax credit for scientific research and experimental development under the *Income Tax Act* as it read on December 1, 1987.

Research and Development Expenditures–Current: Consist of the following non-capital expenses directly related to research work: (a) wages and salaries, (b) direct material, (c) contractors and subcontractors, (d) other direct costs such as factory overhead, (e) payments to designated institutions, (f) payments to granting councils, and (g) payments to other organizations. These elements are described in greater detail in the *Patentees' Guide to Reporting*—Form 3, available on the **PMPRB website** under Regulatory Filings.

Rights Holder: As defined by subsection 79(1) of the *Patent Act*, "a patentee and the person for the time being entitled to the benefit of a certificate of supplementary protection for that invention, and includes, if any other person is entitled to exercise rights in relation to the certificate, that other person in respect of those rights."

Special Access Programme (SAP): A program operated by Health Canada to give practitioners access to medicines that are not approved or otherwise available in Canada.

Voluntary Compliance Undertaking (VCU): A written undertaking by a rights holder to adjust its price to conform to the Board's Guidelines. A VCU represents a promise by a rights holder geared towards a satisfactory resolution of an investigation initiated by Staff as per the Guidelines. A VCU takes into account the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

APPENDIX 2:
PHARMACEUTICAL TRENDS – SALES

TABLE 17. SALES OF PATENTED MEDICINES, 1990 TO 2022

Year	Patented medicine		5-year compound annual growth rate	Sales of patented medicines as a share of all medicine sales*	Patented medicine sales per capita	Change in patented medicine sales per capita	Patented medicine sales per GDP
	Sales ($billions)	Change					
2022	$18.4	5.7%	1.8%	49.0%	$465.12	2.0%	0.666%
2021	$17.4	-1.7%	2.2%	51.0%	$456.14	-3.3%	0.758%
2020	$17.7	3.0%	3.2%	55.4%	$472.00	2.9%	0.801%
2019	$17.2	3.5%	4.5%	57.5%	$458.60	2.7%	0.748%
2018	$16.7	-0.6%	4.5%	59.0%	$446.30	-1.7%	0.751%
2017	$16.8	7.6%	5.4%	61.5%	$454.09	5.4%	0.783%
2016	$15.6	3.3%	3.9%	60.8%	$430.94	2.2%	0.770%
2015	$15.1	9.4%	4.0%	61.6%	$421.80	8.5%	0.760%
2014	$13.8	3.1%	1.2%	59.9%	$388.70	1.8%	0.696%
2013	$13.4	4.2%	1.2%	60.7%	$381.80	2.7%	0.706%
2012	$12.9	0.1%	1.3%	59.2%	$371.80	-1.2%	0.708%
2011	$12.9	3.5%	2.0%	58.3%	$376.10	3.1%	0.729%
2010	$12.4	-4.3%	2.6%	55.8%	$364.70	-5.7%	0.746%
2009	$13.0	2.9%	4.4%	59.6%	$386.90	1.9%	0.829%
2008	$12.6	4.6%	5.4%	61.7%	$379.50	2.9%	0.762%
2007	$12.1	3.2%	6.3%	63.2%	$368.90	2.5%	0.769%
2006	$11.7	7.4%	9.0%	67.8%	$360.00	6.3%	0.784%
2005	$10.9	4.2%	11.6%	70.6%	$338.50	2.8%	0.769%
2004	$10.5	7.8%	14.2%	72.2%	$329.20	7.2%	0.789%
2003	$9.7	9.0%	17.7%	72.7%	$307.00	8.0%	0.776%
2002	$8.9	17.5%	19.2%	67.4%	$284.30	16.0%	0.748%
2001	$7.6	18.9%	20.4%	65.0%	$245.20	19.1%	0.666%
2000	$6.3	16.7%	19.4%	63.0%	$205.90	15.9%	0.571%
1999	$5.4	27.0%	17.6%	61.0%	$177.60	24.3%	0.538%
1998	$4.3	18.9%	12.4%	55.1%	$142.90	15.4%	0.459%

Continued on next page...

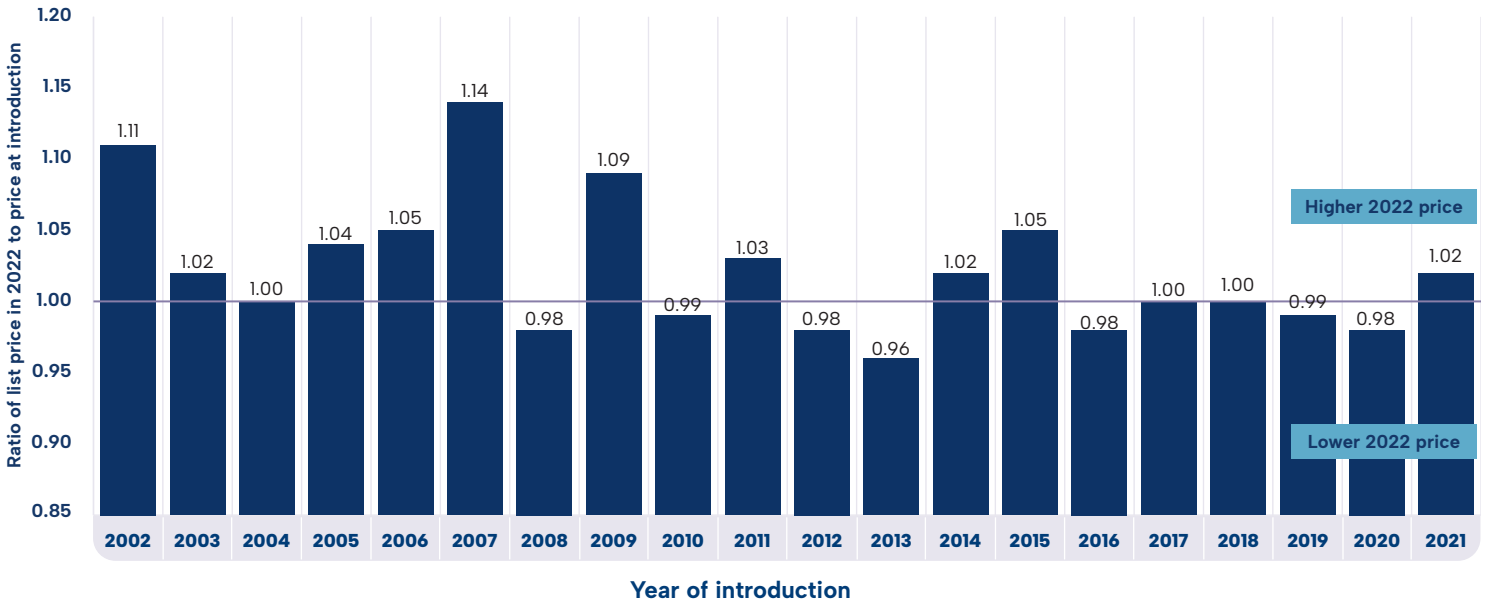
Year	Patented medicine		5-year compound annual growth rate	Sales of patented medicines as a share of all medicine sales*	Patented medicine sales per capita	Change in patented medicine sales per capita	Patented medicine sales per GDP
	Sales ($billions)	Change					
1997	$3.7	22.6%	11.0%	52.3%	$123.70	22.1%	0.409%
1996	$3.0	12.8%	8.4%	45.0%	$101.40	14.2%	0.350%
1995	$2.6	10.8%	8.9%	43.9%	$88.70	7.2%	0.314%
1994	$2.4	-2.1%	—	40.7%	$82.80	-1.4%	0.304%
1993	$2.4	9.4%	—	44.4%	$83.90	7.9%	0.322%
1992	$2.2	14.0%	—	43.8%	$77.70	8.8%	0.307%
1991	$2.0	13.1%	—	43.2%	$71.40	16.0%	0.286%
1990	$1.7	—	—	43.2%	$61.60	—	0.245%

* The denominator in this ratio comprises sales of patented and non-patented brand medicines and patented and non-patented generic medicines. Starting with the estimate for 2005, this value is derived from data contained in IQVIA's MIDAS® database. In previous years, IQVIA data was used to calculate sales of generic medicines only, while sales of non-patented brand products were estimated from data submitted by rights holders. This approach was abandoned because of anomalies related to year-to-year changes in the set of companies reporting to the PMPRB. Ratios reported for years before 2005 likely overstate the patented share, but by only a small amount. This small bias in no way invalidates the strong upward trend evinced by the results for the years 1990 through 2003. Ratios since 2009 have also been revised slightly as a result of data updates from IQVIA—none of these adjustments resulted in a change greater than 0.4%.

Data source: PMPRB; MIDAS® database, 2005–2022, IQVIA (all rights reserved)

APPENDIX 3:
PHARMACEUTICAL TRENDS – CANADIAN LIST PRICE COMPARISONS

FIGURE 36. AVERAGE RATIO OF 2022 LIST PRICE TO INTRODUCTORY LIST PRICE, BY YEAR OF INTRODUCTION



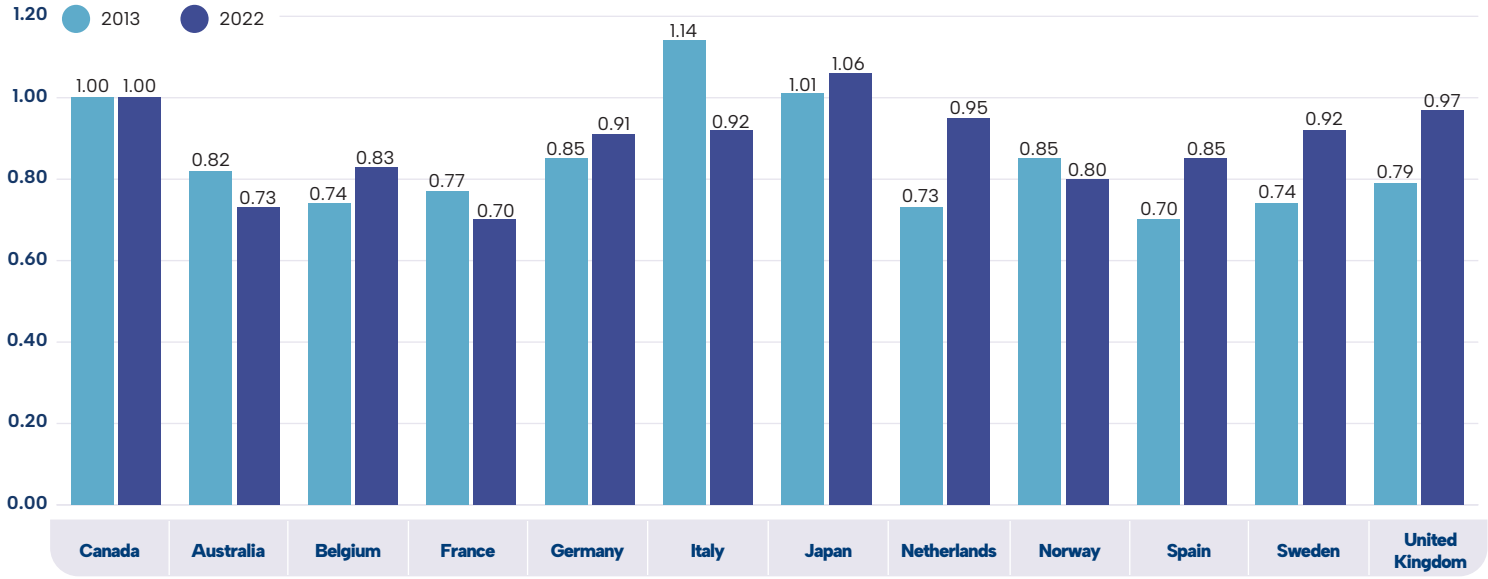
Data source: PMPRB

TABLE 18. AVERAGE FOREIGN-TO-CANADIAN LIST PRICE RATIOS, BILATERAL COMPARISONS, CANADA AND THE PMPRB11, 2022

	Canada	Australia	Belgium	France	Germany	Italy	Japan	Spain	Sweden	Norway	Netherlands	United Kingdom
At market exchange rates												
Average price ratio 2022	1.00	0.73	0.83	0.70	0.91	0.92	1.06	0.95	0.80	0.85	0.92	0.97
Average price ratio 2021	1.00	0.71	0.88	0.69	0.92	0.98	0.90	0.96	0.81	0.88	0.77	0.95
At purchasing power parities												
Average price ratio 2022	1.00	0.69	0.99	0.86	1.08	1.27	1.23	1.35	0.82	0.70	1.04	1.09
Average price ratio 2021	1.00	0.67	1.03	0.85	1.11	1.25	0.98	1.32	0.86	0.82	0.86	1.08
Number of patented medicines compared 2022 (DINs)	982*	505	548	510	735	609	436	725	644	695	675	724
Sales ($millions)	$17,784.6	$14,419.6	$14,084.9	$11,574.8	$15,357.9	$14,462.5	$12,060.0	$14,305.0	$11,843.1	$15,303.0	$15,254.8	$15,216.5

Note: 2021 prices for Australia, Belgium, Japan, Spain, Norway, and the Netherlands were sourced from the IQVIA MIDAS® database.
* Consistent with the methodology used throughout the Pharmaceutical Trends section, only medicines that reported to the PMPRB in 2022 and had available Canadian sales data at the time of the analysis were considered here. For the list price analysis, only medicines from this group with a list price available in Canada were used. This is a subsection of the total number of medicines that reported to the PMPRB in 2022 and, as such, may not match the total reported in Table 4.
Data source: PMPRB; MIDAS® database, 2022, IQVIA (all rights reserved)

FIGURE 37. AVERAGE FOREIGN-TO-CANADIAN LIST PRICE RATIOS, CANADA AND THE PMPRB11, 2013 AND 2022



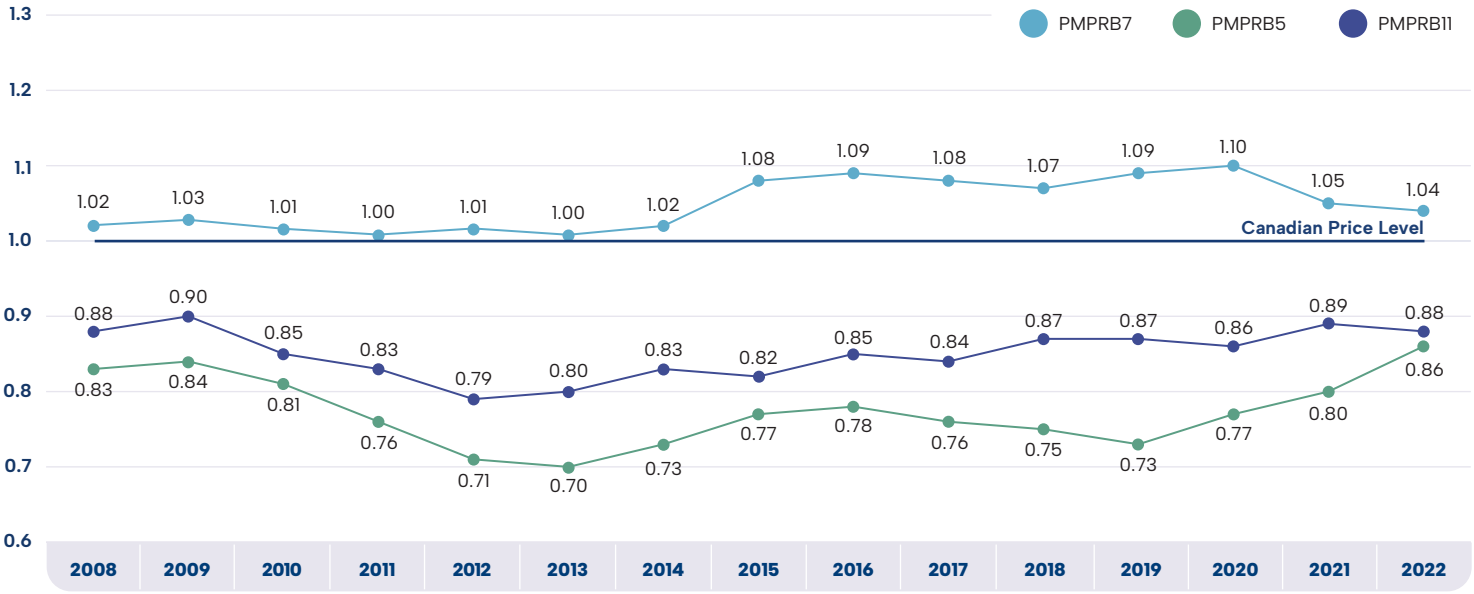
Note: 2013 prices for Australia, Belgium, Japan, Spain, Norway, and the Netherlands are sourced from the IQVIA MIDAS® database.
Data source: PMPRB, MIDAS® database, 2013 and 2022, IQVIA (all rights reserved)

TABLE 19. AVERAGE FOREIGN-TO-CANADIAN LIST PRICE RATIOS, MULTILATERAL COMPARISONS, 2022

	Median	Minimum	Maximum	Mean
Average price ratio at market exchange rates	0.88	0.63	1.24	0.89
Average price ratio at purchasing power parities	1.00	0.63	1.54	1.02
Number of patented medicines	860	860	860	860
Sales ($millions)	$17,238.94	$17,238.94	$17,238.94	$17,238.94

Data source: PMPRB

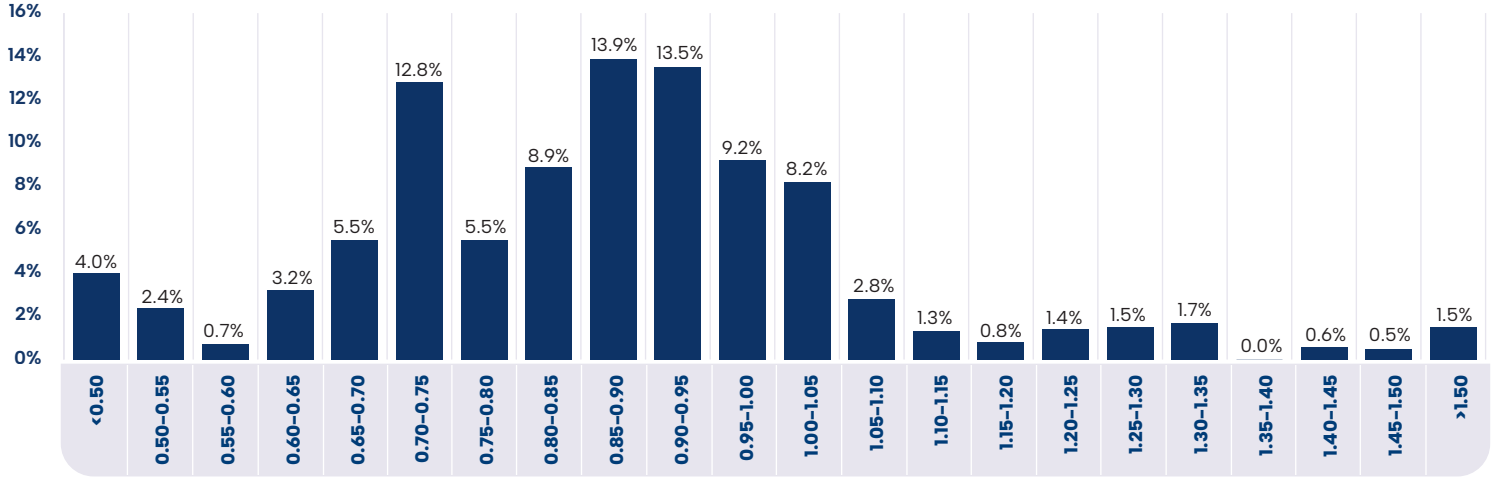
FIGURE 38. AVERAGE RATIO OF MEDIAN INTERNATIONAL PRICE (MIP) TO CANADIAN LIST PRICE, AT MARKET EXCHANGE RATES, PMPRB7, PMPRB5, AND PMPRB11, 2008 TO 2022



Note: PMPRB7 is France, Germany, Italy, Sweden, Switzerland, the United Kingdom (UK), and the United States (US). PMPRB5 removes Switzerland and the US. PMPRB11 is Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, and the UK.

Data source: PMPRB; MIDAS® database, 2008–2022, IQVIA (all rights reserved)

FIGURE 39. RANGE DISTRIBUTION, SHARE OF SALES BY MIP-TO-CANADIAN LIST PRICE RATIO, 2022



Data source: PMPRB

APPENDIX 4:
RESEARCH AND DEVELOPMENT

TABLE 20. RANGE OF R&D-TO-SALES RATIOS BY NUMBER OF REPORTING COMPANIES AND TOTAL SALES REVENUE, 2022 AND 2021

Range: R&D-to-sales ratio	Number of reporting companies: 2022	Sales revenues: 2022 ($millions)	Share: 2022 (%)	Number of reporting companies: 2021	Sales revenues: 2021 ($millions)	Share: 2021 (%)
0%	43	$3,180.7	10.9%	44	$3,017.2	11.0%
≤10%	41	$24,328.1	83.5%	43	$23,160.3	84.3%
>10%	16	$1,636.1	5.6%	13	$1,301.0	4.7%
Total*	**100**	**$29,144.9**	**100%**	**100**	**$27,478.5**	**100%**

* Values may not add to totals due to rounding.
Data source: PMPRB

FIGURE 40. CURRENT R&D EXPENDITURES ($MILLIONS) BY TYPE OF RESEARCH, 1988 TO 2022

Data source: PMPRB

TABLE 21. CURRENT R&D EXPENDITURES BY PROVINCE/TERRITORY, 2022

Province	Expenditures: All rights holders ($thousands)	Regional share	Expenditures: Innovative Medicines Canada ($thousands)	Regional share
Newfoundland and Labrador	$1,254.08	0.142%	$729.09	0.100%
Prince Edward Island	$191.91	0.022%	$0.00	0.000%
Nova Scotia	$9,652.49	1.093%	$7,631.92	1.051%
New Brunswick	$2,077.18	0.235%	$1,540.88	0.212%
Quebec	$262,905.26	29.782%	$232,062.74	31.959%
Ontario	$419,925.56	47.570%	$321,473.70	44.272%
Manitoba	$4,632.47	0.525%	$2,679.43	0.369%
Saskatchewan	$1,740.10	0.197%	$460.96	0.063%
Alberta	$122,886.26	13.921%	$116,368.51	16.026%
British Columbia	$57,416.23	6.504%	$43,181.09	5.947%
Territories	$70.38	0.008%	$0.00	0.000%
Canada*	**$882,751.92**	**100%**	**$726,128.32**	**100%**

* Provincial/territorial values may not add to totals for Canada due to rounding.

Data source: PMPRB

TABLE 22. CURRENT R&D EXPENDITURES BY PERFORMER AND PROVINCE/TERRITORY, 2022

Province		Rights holders	Other companies	Universities	Hospitals	Others
Newfoundland and Labrador	Expenditure ($thousands)	$633.19	$426.97	$62.52	$6.45	$124.95
	Share	50.5%	34.0%	5.0%	0.5%	10.0%
Prince Edward Island	Expenditure ($thousands)	$93.39	$98.52	$0.00	$0.00	$0.00
	Share	48.7%	51.3%	0.0%	0.0%	0.0%
Nova Scotia	Expenditure ($thousands)	$1,297.74	$2,501.16	$1,234.55	$424.24	$4,194.78
	Share	13.4%	25.9%	12.8%	4.4%	43.5%
New Brunswick	Expenditure ($thousands)	$808.99	$562.35	$46.81	$168.71	$490.31
	Share	38.9%	27.1%	2.3%	8.1%	23.6%
Quebec	Expenditure ($thousands)	$74,158.76	$94,019.32	$17,970.49	$26,519.88	$50,236.80
	Share	28.2%	35.8%	6.8%	10.1%	19.1%
Ontario	Expenditure ($thousands)	$241,635.82	$76,592.97	$29,632.67	$38,395.55	$33,668.55
	Share	57.5%	18.2%	7.1%	9.1%	8.0%
Manitoba	Expenditure ($thousands)	$2,769.04	$372.18	$687.27	$609.11	$194.88
	Share	59.8%	8.0%	14.8%	13.1%	4.2%
Saskatchewan	Expenditure ($thousands)	$651.65	$ 507.02	$410.07	$0.00	$171.35
	Share	37.4%	29.1%	23.6%	0.0%	9.8%
Alberta	Expenditure ($thousands)	$94,621.40	$14,344.37	$2,631.69	$4,360.46	$6,928.34
	Share	77.0%	11.7%	2.1%	3.5%	5.6%
British Columbia	Expenditure ($thousands)	$29,869.61	$14,404.97	$2,615.83	$2,580.16	$7,945.67
	Share	52.0%	25.1%	4.6%	4.5%	13.8%
Territories	Expenditure ($thousands)	$70.38	$0.00	$0.00	$0.00	$0.00
	Share	100.0%	0.0%	0.0%	0.0%	0.0%
Canada*	**Expenditure ($thousands)**	**$446,609.97**	**$203,829.83**	**$55,291.90**	**$73,064.56**	**$103,955.62**
	Share	**50.6%**	**23.1%**	**6.3%**	**8.3%**	**11.8%**

Note: For each jurisdiction, the share for each category represents the percentage of total R&D expenditures for the given province or territory (or nationally for the total R&D in Canada).

* Provincial/territorial expenditures may not add to totals for Canada and shares across individual rows may not add to 100% due to rounding.

Total R&D expenditures are the sum of current expenditures and capital expenditures (equipment + depreciation).

Data source: PMPRB

The document that is being electronically submitted to the Tribunal is an electronic version of a document that has been signed by the affiant. The signed document in paper copy is available and will be produced if requested by the Tribunal.

Jonathan Wall
Goodmans LLP

File No. CT-2024-006

COMPETITION TRIBUNAL

IN THE MATTER OF the Competition Act, R.S.C. 1985, c. C-34 (the"**Act**");

AND IN THE MATTER OF an application by JAMP Pharma Corporation for an order pursuant to section 103.1 of the Act granting leave to bring an application under section 79 of the Act;

AND IN THE MATTER OF an application by JAMP Pharma Corporation for an order pursuant to section 79 of the Act;

BETWEEN:

JAMP PHARMA CORPORATION

Applicant

– and –

JANSSEN INC.

Respondent

AFFIDAVIT OF EMILY SEABY
(Pursuant to s. 103.1 of the *Competition Act*)

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