

**SUPREME COURT OF CANADA**

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| **Citation:** Katz Group Canada Inc. *v.* Ontario (Health and Long-Term Care), 2013 SCC 64, [2013] 3 S.C.R. 810 | **Date:** 20131122  **Docket:** 34647, 34649 |

**Between:**

**Katz Group Canada Inc.,**

**Pharma Plus Drug Marts Ltd. and Pharmx Rexall Drug Stores Ltd.**

Appellants

and

**Minister of Health and Long-Term Care,**

**Lieutenant Governor-In-Council of Ontario and Attorney General of Ontario**

Respondents

**And Between:**

**Shoppers Drug Mart Inc.,**

**Shoppers Drug Mart (London) Limited and Sanis Health Inc.**

Appellants

and

**Minister of Health and Long-Term Care,**

**Lieutenant Governor-In-Council of Ontario and Attorney General of Ontario**

Respondents

**Coram:** McLachlin C.J. and LeBel, Abella, Rothstein, Cromwell, Moldaver and Wagner JJ.

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| **Reasons for Judgment:**  (paras. 1 to 51) | Abella J. (McLachlin C.J. and LeBel, Rothstein, Cromwell, Moldaver and Wagner JJ. concurring) |

Katz Group Canada Inc. *v.* Ontario (Health and Long‑Term Care), 2013 SCC 64, [2013] 3 S.C.R. 810

Katz Group Canada Inc.,

Pharma Plus Drug Marts Ltd. and

Pharmx Rexall Drug Stores Ltd. Appellants

v.

Minister of Health and Long‑Term Care,

Lieutenant Governor‑in‑Council of Ontario and

Attorney General of Ontario Respondents

‑ and ‑

Shoppers Drug Mart Inc.,

Shoppers Drug Mart (London) Limited and Sanis Health Inc. Appellants

v.

Minister of Health and Long‑Term Care,

Lieutenant Governor‑in‑Council of Ontario and

Attorney General of Ontario Respondents

**Indexed as: Katz Group Canada Inc. *v.* Ontario (Health and Long‑Term Care)**

2013 SCC 64

File Nos.: 34647, 34649.

2013:  May 14; 2013:  November 22.

Present: McLachlin C.J. and LeBel, Abella, Rothstein, Cromwell, Moldaver and Wagner JJ.

on appeal from the court of appeal for ontario

*Food and drugs — Regulations — Validity — Province of Ontario enacting Regulations to effectively ban the sale of private label drugs by pharmacies — Purpose of Regulations to reduce drug prices — Whether Regulations are ultra vires on the ground that they are inconsistent with the statutory scheme and mandate — Drug Interchangeability and Dispensing Fee Act Regulation, R.R.O. 1990, Reg. 935, s. 9 — Ontario Drug Benefit Act Regulation, O. Reg. 201/96, s. 12.0.2.*

For decades, Ontario has been involved in an ongoing struggle to control rising drug costs. Generic drugs have been a key part of the strategy for dealing with this problem. Persistent market practices, however, have kept generic prices high. In Ontario, the result has been an episodic and totemic tug‑of‑war between regulators and those engaged in the manufacture, distribution and sale of generic drugs.

In 1985, two complementary and intersecting statutes were introduced together to address the problem of rising drug prices for consumers: the *Drug Interchangeability and Dispensing Fee Act* and the *Ontario Drug Benefit Act*. The *Drug Interchangeability and Dispensing Fee Act* empowers the Ministry to designate a cheaper generic drug as “interchangeable” with a more expensive brand‑name drug. Pharmacists must dispense the cheaper interchangeable generic to customers unless the prescribing physician specifies “no substitution” or the customer agrees to pay the extra cost of the brand name. This statute also limits the dispensing fees that pharmacies can charge private customers.

The *Ontario Drug Benefit Act* governs the Ontario Drug Benefit Program whereby the province reimburses pharmacies when they dispense prescription drugs at no charge to “eligible persons” — primarily seniors and persons on social assistance. All drugs for which Ontario will provide reimbursement, along with the price that Ontario will pay for them, are listed in the Formulary. When a pharmacy dispenses a listed drug to an eligible person, the *Ontario Drug Benefit Act* requires Ontario to reimburse the pharmacy for an amount based on the Formulary price of the drug plus a prescribed mark‑up and prescribed dispensing fee. This legislative scheme effectively creates two markets in Ontario for brand name and generic drugs. The private market consists of individuals buying drugs at their own expense or for reimbursement by private drug insurance plans. The “public market” is the government‑funded Ontario Drug Benefit Program. Generic drugs reach consumers in Ontario’s private and public markets through a supply chain that involves several participants regulated at the federal level, the provincial level, or both. They are: fabricators, who make the generic drugs; manufacturers, who sell generic drugs under their own name to wholesalers or directly to pharmacies; wholesalers, who buy drugs from manufacturers to distribute to pharmacies; and pharmacies, who buy drugs from wholesalers or manufacturers and dispense them to their customers.

Before 2006, the price at which manufacturers could apply to list generic drugs in the Formulary was capped by regulations under the two statutes. In order to be competitive, manufacturers would, however, give pharmacies a substantial rebate to induce them to buy their products. The price that manufacturers charged — and customers paid — was thereby artificially increased to the extent of the rebates. In 2006, in order to stop this inflationary effect on generic drug prices, the two statutes and the Regulations under them were amended to prohibit rebates. The expected savings did not occur and manufacturers continued to charge high prices for generic drugs. Instead of the rebates, manufacturers were now paying pharmacies $800 million annually in professional allowances. Amendments were therefore introduced in 2010 eliminating the “professional allowances” exception.

The Regulations to the two statutes were also amended to preventpharmacies from controlling manufacturers who sell generic drugs under their own name but do not fabricate them. This was done by creating a category designated as “private label products”, which includes products sold but not fabricated by a manufacturer which does not have an arm’s length relationship with drug wholesalers or pharmacies. Under the Regulations, private label products cannot be listed in the Formulary or designated as interchangeable.

Sanis Health Inc., a subsidiary of Shoppers Drug Mart, was incorporated by Shoppers for the purpose of buying generic drugs from third party fabricators and selling them under the Sanis label in Shoppers Drug Mart stores. Katz Group Canada Inc., Pharma Plus Drug Marts Ltd. and Pharmx Rexall Drug Stores Ltd. also operate pharmacies in Ontario and, like Shoppers, have taken steps to set up their own “private label” manufacturer. In 2010, Sanis applied to list several generic drugs in the Formulary and have them designated as “interchangeable”. Its application was rejected, however, because those generic drugs were “private label products”. Shoppers and Katz challenged the Regulations that banned the sale of private label products as being *ultra vires* on the grounds that they were inconsistent with the purpose and mandate of the statutes. The challenge succeeded in the Divisional Court. The Court of Appeal reversed the decision.

*Held*: The appeal should be dismissed.

A successful challenge to the *vires* of Regulations requires that they be shown to be inconsistent with the objective of the enabling statute orthe scope of the statutory mandate. Regulations benefit from a presumption of validity. This presumption has two aspects: it places the burden on challengers to demonstrate the invalidity of regulations rather than on regulatory bodies to justify them; and it favours an interpretative approach that reconciles the regulation with its enabling statute so that, where possible, the regulation is construed in a manner which renders it *intra vires*. Both the challenged regulation and the enabling statute should be interpreted using a broad and generous approach consistent with this Court’s approach to statutory interpretation generally. This inquiry does not involve assessing the policy merits of the Regulations to determine whether they are necessary, wise or effective in practice. Nor is it an inquiry into the underlying political, economic, social or partisan considerations.

In this case, the original legislative intent animating the two statutes was to control the cost of prescription drugs in Ontario without compromising safety. As the legislative history shows, attempts were made to promote transparent pricing and eliminate price inflation along the drug supply chain, all in pursuit of the ultimate objective of lowering drug costs. Thepurpose of the 2010 Regulations banning private label products was to prevent another possible mechanism for circumventing the ban on the rebates that had keptdrug prices inflated. If pharmacies were permitted to create their own affiliated manufacturers whom they controlled, they would be directly involved in setting the Formulary prices and have strong incentives to keep those prices high.

The 2010 private label Regulations contribute to the legislative pursuit of transparent drug pricing. They fit into this strategy by ensuring that pharmacies make money exclusively from providing professional health care services, instead of sharing in the revenues of drug manufacturers by setting up their own private label subsidiaries. The Regulations were therefore consistent with the statutory purpose of reducing drug costs.

**Cases Cited**

**Referred to:** *Waddell v. Governor in Council* (1983), 8 Admin. L.R. 266; *United Taxi Drivers’ Fellowship of Southern Alberta v. Calgary (City)*, 2004 SCC 19, [2004] 1 S.C.R. 485; *Glykis v. Hydro‑Québec*, 2004 SCC 60, [2004] 3 S.C.R. 285; *Jafari v. Canada (Minister of Employment and Immigration)*, [1995] 2 F.C. 595; *Ontario Federation of Anglers & Hunters v. Ontario (Ministry of Natural Resources)* (2002), 211 D.L.R. (4th) 741; *Thorne’s Hardware Ltd. v. The Queen*, [1983] 1 S.C.R. 106; *CKOY Ltd. v. The Queen*, [1979] 1 S.C.R. 2; *Alaska Trainship Corp. v. Pacific Pilotage Authority*, [1981] 1 S.C.R. 261; *Re Doctors Hospital and Minister of Health* (1976), 12 O.R. (2d) 164; *Shell Canada Products Ltd. v. Vancouver (City)*, [1994] 1 S.C.R. 231; *Municipal Corporation of City of Toronto v. Virgo*, [1896] A.C. 88; *Forget v. Quebec (Attorney General)*, [1988] 2 S.C.R. 90.

**Statutes and Regulations Cited**

*Drug Interchangeability and Dispensing Fee Act*, R.S.O. 1990, c. P.23, ss. 12.1, 14(1), (8).

*Food and Drug Regulations*, C.R.C., c. 870.

*Legislation Act, 2006*, S.O. 2006, c. 21, Sch. F, ss. 64, 82.

O. Reg. 201/96, ss. 1, 1(6) [rep. & sub. O. Reg. 220/10, s. 1(1)], 12.0.2(1), (2) “private label product” [ad. O. Reg. 220/10, s. 3].

*Ontario Drug Benefit Act*, R.S.O. 1990, c. O.10, ss. 0.1, 1(1), 1.2(2)(a), 1.3, 11.5, 18(1), (6).

R.R.O. 1990, Reg. 935, ss. 2, 9(1), (2) “private label product” [ad. O. Reg. 221/10, s. 5].

*Transparent Drug System for Patients Act, 2006*, S.O. 2006, c. 14.

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APPEAL from a judgment of the Ontario Court of Appeal (MacPherson, Epstein and Karakatsanis JJ.A.), 2011 ONCA 830, 109 O.R. (3d) 279, 286 O.A.C. 68, 345 D.L.R. (4th) 277, 37 Admin. L.R. (5th) 101, [2011] O.J. No. 5894 (QL), 2011 CarswellOnt 14816, setting aside a decision of Whalen, Molloy and Swinton JJ., 2011 ONSC 615, [2011] O.J. No. 480 (QL), 2011 CarswellOnt 720. Appeal dismissed.

*Terrence J. O’Sullivan* and *M. Paul Michell*, for the appellants Katz Group Canada Inc., Pharma Plus Drug Marts Ltd. and Pharmx Rexall Drug Stores Ltd.

*Mahmud Jamal*, *Craig T. Lockwood*, *Eric Morgan* and *W. David Rankin*, for the appellants Shoppers Drug Mart Inc., Shoppers Drug Mart (London) Limited and Sanis Health Inc.

*Lise G. Favreau*, *Kim Twohig* and *Kristin Smith*, for the respondents.

The judgment of the Court was delivered by

1. Abella J. — Canada spends more on prescription drugs per capita than almost all members of the Organisation for Economic Co-operation and Development.[[1]](#footnote-1) Prescription drugs are the second largest area of health care spending.[[2]](#footnote-2) Drug costs accounted for approximately 9.5% of government health care expenses in 1985. By 2010, that number had risen to 15.9%.[[3]](#footnote-3)
2. A key part of the strategy for controlling drug costs has been to replace brand-name drugs with generic drugs, in the expectation that generic drugs would be significantly cheaper. Those expectations were, however, challenged by persistent market practices that kept generic prices high. In Ontario, the result has been an episodic tug-of-war between regulators and those engaged in the manufacture, distribution and sale of generic drugs. This appeal arises out of one of those regulatory episodes.

Background

1. The sale and pricing of generic drugs is provincially regulated. In Ontario, two complementary and intersecting statutes were introduced together in 1985 to address the problem of rising drug prices: the *Drug Interchangeability and Dispensing Fee Act*, R.S.O. 1990, c. P.23, and the *Ontario Drug Benefit Act*, R.S.O. 1990, c. O.10 (“*Acts*”).
2. The *Drug Interchangeability and Dispensing Fee Act* ensures that patients in Ontario receive generic drugs rather than equivalent but more expensive brand-name drugs. It does so by empowering the Executive Officer of the Ministry of Health and Long-Term Care to designate a generic drug as “interchangeable” with a brand-name drug. Pharmacists must dispense the cheaper interchangeable generic to customers unless the prescribing physician specifies “no substitution” or the customer agrees to pay the extra cost of the brand-name. The *Act* also limits the dispensing fees that pharmacies can charge private customers.
3. The *Ontario Drug Benefit Act* governs the Ontario Drug Benefit Program, whereby the province reimburses pharmacies when they dispense prescription drugs at no charge to “eligible persons” — primarily seniors and persons on social assistance. The list of all drugs for which Ontario will provide reimbursement, along with the price that Ontario will pay for them, is called the Formulary. The Executive Officer is responsible for listing drugs in the Formulary and setting their price by agreement with the drugs’ manufacturers. When a pharmacy dispenses a listed drug to an eligible person, the *Ontario Drug Benefit Act* requires Ontario to reimburse the pharmacy for an amount based on the Formulary price of the drug plus a prescribed mark-up and prescribed dispensing fee.
4. This legislative scheme effectively creates two markets in Ontario for brand-name and generic drugs. The “private market” consists of individuals buying drugs at their own expense or for reimbursement by private drug insurance plans. This market includes employer benefit plans, which in 2010 provided drug coverage for 8.6 million Ontario employees and their families at a cost of $4 billion to employers. Generic drugs, in order to be in the private market, must receive Health Canada approval for safety and effectiveness, and must be designated as “interchangeable” by Ontario’s Executive Officer.
5. The “public market” is the government-funded Ontario Drug Benefit Program. To be in this market, generic drugs must be approved by Health Canada, designated by Ontario as interchangeable, *and* listed in the province’s Formulary. In 2010, the Ontario Drug Benefit Program provided drug coverage for 2.5 million people for the purchase of 3,300 drugs listed in the Formulary at a cost of $3.7 billion.
6. Generic drugs reach consumers in Ontario’s private and public markets through a supply chain that involves several participants regulated at the federal level, the provincial level, or both. They are:
   * Fabricators, who make the generic drugs.Fabricators are licensed federally under the *Food and Drug Regulations*, C.R.C., c. 870.
   * Manufacturers, who are licensed under the federal *Food and Drug Regulations* to sell generic drugs under their own name to wholesalers or directly to pharmacies. Manufacturers are responsible for regulatory compliance: having the drug approved by Health Canada, and having it designated as interchangeable and listed in the Formulary. A manufacturer can either make drugs itself, in which case it is also regulated as a fabricator, or it can buy the drugs from a fabricator. The price at which manufacturers sell the drugs to wholesalers or pharmacies is regulated under the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act*. The price at which manufacturers buy drugs from fabricators is not regulated.
   * Wholesalers, who are licensed under the federal *Food and Drug Regulations* to buy drugs from manufacturers to distribute to pharmacies. The prices at which wholesalers buy and sell drugs are regulated under the Ontario *Acts*. Their role is not implicated in the particular issue before this Court.
   * Pharmacies, who buy drugs from wholesalers or manufacturers and dispense them to their customers. The term is used in these reasons to refer to pharmacy operators and to companies that own, operate or control pharmacies. The prices at which pharmacies buy drugs and dispense them to customers are regulated under the Ontario *Acts*.
7. The *Drug Interchangeability and Dispensing Fee Act* and the *Ontario Drug Benefit Act* give the Lieutenant Governor in Council the authority to make regulations, including the authority to prescribe the conditions drugs must meet in order to be sold in Ontario. Ontario has used that regulatory authority to impose price controls along the drug supply chain.
8. Prior to 2006, the price at which manufacturers could apply to list generic drugs in the Formulary was capped by regulations under the *Acts* at effectively 63% of the price of the brand-name drug. Pharmacies would buy drugs from manufacturers at the Formulary price, and dispense them to customers at the Formulary price, plus regulated mark-ups and dispensing fees. In order to be competitive, manufacturers would, however, give pharmacies a substantial rebate so that they would buy their products. The price that manufacturers charged — and customers paid — was thereby artificially increased to the extent of the rebates. The rebates were up to $600-800 million annually, and were said to account for 40% of the price manufacturers charged for drugs.
9. In order to stop this inflationary effect on generic drug prices, in 2006, the *Ontario Drug Benefit Act*, the *Drug Interchangeability and Dispensing Fee Act*, and the Regulations under them were amended to prohibit rebates.[[4]](#footnote-4) The amendments were introduced as the *Transparent Drug System for Patients Act, 2006*, S.O. 2006, c. 14*.* Theyalso added a “Principles” clause to the *Ontario Drug Benefit Act*,[[5]](#footnote-5) which stated that the public drug system “aims to operate *transparently* to the extent possible for all persons with an interest in the system, including . . . consumers, *manufacturers*, wholesalers *and pharmacies*” and “aims to consistently achieve value-for-money and ensure the best use of resources at every level of the system”.
10. The legislature sought to terminate one major source of revenue for pharmacies — payments from drug manufacturers — and replace it with government reimbursement for providing professional health care services. The amendments made the reimbursement of pharmacies for professional services a function of the Executive Officer, established a Pharmacy Council to advise the Minister primarily on this issue, and created a new regulation-making power allowing the Lieutenant Governor in Council to govern all aspects of professional services. Ontario also increased the prescribed dispensing fees in the public market.
11. In the expectation that the elimination of rebates would lead manufacturers to lower their prices, the Ontario government also reduced the price cap imposed by the Regulations to 50% in the public market and removed the cap entirely in the private market. Manufacturers could, however, give pharmacies “professional allowances” for direct patient care programs.
12. But the expected savings did not occur and manufacturers continued to charge high prices for generic drugs. Ontario’s Ministry of Health and Long-Term Care found in 2007 that some of the leading generic drugs were three times more expensive in Ontario than in France, Germany and the United Kingdom, five times more expensive than in the United States, and twenty-two times more expensive than in New Zealand. In fact, as a Competition Bureau Report concluded, new generic drugs were entering the uncapped private market at a price higher than the previous cap of 63% (*Benefiting from Generic Drug Competition in Canada: The Way Forward* (2008), at p. 10).
13. In addition, instead of the rebates, manufacturers were now paying pharmacies $800 million annually in professional allowances. As a result, the professional allowance exception was identified as yet another inflationary loophole. Audits of 206 pharmacies showed that all of them were in violation of the rules pertaining to professional allowances, and 70% of the funds provided by manufacturers on this basis went towards higher salaries and store profits, instead of being used for patient care. The then Minister of Health, the Hon. Deborah Matthews, concluded that the continuing payments by drug manufacturers to pharmacies were the major reason Ontario still had inflated generic drug prices relative to comparable countries. In her view, drug prices could be cut by 50% if the payments were eliminated (Legislative Assembly of Ontario, *Official Report of Debates (Hansard)*, Nos. 13, 19 and 23, 2nd Sess., 39th Parl., April 12, 21 and 28, 2010).
14. Amendments were therefore introduced in 2010 to both *Acts* and to the Regulations, eliminating the “professional allowances” exception. Together with the 2006 ban on rebates, this prevented manufacturers from giving pharmacies any benefits for purchasing their drugsother than small prescribed discounts. At the same time, Ontario reduced the price cap imposed by the Regulations to 25% in the public market and re-introduced the price cap in the private market. Ontario also amended the Regulations to provide more reimbursement to pharmacies for professional services by further increasing the prescribed dispensing fees in the public market, and by directing the Executive Officer to pay an additional service fee on most claims in the public market until March 31, 2013 in “recognition of the transition to a pharmacy reimbursement model aimed at supporting professional services” (O. Reg. 220/10, s. 1(1)). The government also allocated $100 million in funding for the development of professional services by pharmacies.
15. The Regulations to the *Ontario Drug Benefit Act*[[6]](#footnote-6) and the *Drug Interchangeability and Dispensing Fee Act*[[7]](#footnote-7) were also amended to preventpharmacies from controlling manufacturers who sell generic drugs under their own name but do not fabricate them. This was done by creating a category designated as “private label products”, which were defined in both sets of Regulations as follows:

“private label product” includes a drug product in respect of which,

(a) the manufacturer applying for the designation of the product as a listed drug product does not directly fabricate the product itself, and,

(i) is not controlled by a person that directly fabricates the product, or

(ii) does not control the person that directly fabricates the product, and

(b) either,

(i) the manufacturer does not have an arm’s-length relationship with a wholesaler, an operator of a pharmacy or a company that owns, operates or franchises pharmacies, or

(ii) the product is to be supplied under a marketing arrangement associating the product with a wholesaler or one or more operators of pharmacies or companies that own, operate or franchise pharmacies.

(O. Reg. 220/10, s. 3; O. Reg. 221/10, s. 5)

1. Private label products cannot be listed in the Formulary[[8]](#footnote-8) or designated as interchangeable.[[9]](#footnote-9) These restrictions essentially ban the sale of private label drugs in the private and public markets in Ontario and are at the heart of this appeal.
2. Sanis Health Inc., a subsidiary of the Canadian public company Shoppers Drug Mart Corp., is a manufacturer of private label products. It was incorporated by Shoppers for the purpose of buying generic drugs from third party fabricators and selling them under the Sanis label in Shoppers Drug Mart stores. Sanis entered into cross-licensing and fabrication agreements with Cobalt Pharmaceuticals Inc. and Mylan Pharmaceuticals ULC, two manufacturers which currently fabricate generic drugs and sell them in Ontario. Pursuant to these arrangements, Sanis would rely on Cobalt and Mylan to fabricate generic drugs for it and would piggy-back onto their regulatory submissions as manufacturers to obtain its own Health Canada approval.
3. In 2010, Sanis applied to the Executive Officer to list several generic drugs in the Formulary and have them designated as interchangeable. The Executive Officer rejected its applicationfor the following reasons:

As you may be aware, the ministry recently posted a notice of proposed regulations on April 8, 2010 to amend the regulations under the [*Drug Interchangeability and Dispensing Fee Act*] and the [*Ontario Drug Benefit Act*]. These regulations propose that it is a condition of being designated under the [*Drug Interchangeability and Dispensing Fee Act*] that a product is not a private label product, and it is a condition of a product being a listed drug product under the [*Ontario Drug Benefit Act*] that it not be a private label product. These regulations will come into effect on July 1, 2010.

It seems to me that [Sanis’ products] would be “private label products” as defined in the regulations. Sanis does not directly fabricate the Products and it does not have an arm’s length relationship with a company that owns, operates or franchises pharmacies.

The purpose of the regulations is to prevent a pharmacy-controlled or related entity purchasing drug products from a person that actually makes the product at lower prices than the drug benefit price on the ODB Formulary without providing any price reduction to patients, insurers, employers, the Government of Ontario, or other payors.

The government’s amendments to Ontario’s drug regulations seek to encourage manufacturers to provide lower prices to Ontario patients. With private label products, the price reductions that Sanis presumably enjoys would not be passed onto end-payors such as government, insurers and patients. Instead, it seems that profits would be retained within pharmacy-controlled organizations without benefiting consumers. While that would not be a “rebate” as defined in the legislation, it is a similar problem that the provisions against rebates seek to prevent. Further, there is a concern that Shoppers Drug Mart pharmacies could have an interest in dispensing [Sanis products] in preference to others, which raises the potential for a conflict of interest.

As a result, I do not intend to designate the Products as interchangeable under the [*Drug Interchangeability and Dispensing Fee Act*] or as listed drug products under the [*Ontario Drug Benefit Act*].

1. Katz Group Canada Inc., Pharma Plus Drug Marts Ltd. and Pharmx Rexall Drug Stores Ltd. operate the Pharma Plus and Rexall pharmacies in Ontario and, like Shoppers, have taken steps to set up their own private label manufacturer. They haveindicated that they intend to follow the same general business model as Sanis.
2. Shoppers and Katz challenged the private label regulations as being *ultra vires* on the grounds that they were inconsistent with the statutory purpose and mandate. They succeeded in the Divisional Court, where Molloy J. concluded that the private label regulations were neither consistent with the purposes of the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act*, nor authorised by the regulation-making provisions. This decision was reversed in the Court of Appeal, where a majority (MacPherson and Karakatsanis JJ.A.) found that the private label regulations were *intra vires*.
3. I agree with MacPherson and Karakatsanis JJ.A. and would dismiss the appeal.

Analysis

1. A successful challenge to the *vires* of regulations requires that they be shown to be inconsistent with the objective of the enabling statute orthe scope of the statutory mandate (Guy Régimbald, *Canadian Administrative Law* (2008), at p. 132). This was succinctly explainedby Lysyk J.:

In determining whether impugned subordinate legislation has been enacted in conformity with the terms of the parent statutory provision, it is essential to ascertain the scope of the mandate conferred by Parliament, having regard to the purpose(s) or objects(s) of the enactment as a whole. The test of conformity with the Act is not satisfied merely by showing that the delegate stayed within the literal (and often broad) terminology of the enabling provision when making subordinate legislation. The power-conferring language must be taken to be qualified by the overriding requirement that the subordinate legislation accord with the purposes and objects of the parent enactment read as a whole.

(*Waddell v. Governor in Council* (1983), 8 Admin. L.R. 266, at p. 292)

1. Regulations benefit from a presumption of validity (Ruth Sullivan, *Sullivan on the Construction of Statutes* (5th ed. 2008), at p. 458). This presumption has two aspects: it places the burden on challengers to demonstrate the invalidity of regulations, rather than on regulatory bodies to justify them (John Mark Keyes, *Executive Legislation* (2nd ed. 2010), at pp. 544-50); and it favours an interpretative approach that reconciles the regulation with its enabling statute so that, *where possible*, the regulation is construed in a manner which renders it *intra vires* (Donald J. M. Brown and John M. Evans, *Judicial Review of Administrative Action in Canada*, vol. 3 (loose-leaf), at 15:3200 and 15:3230).
2. Both the challenged regulation and the enabling statute should be interpreted using a “broad and purposive approach . . . consistent with this Court’s approach to statutory interpretation generally” (*United Taxi Drivers’ Fellowship of Southern Alberta v. Calgary (City)*, 2004 SCC 19, [2004] 1 S.C.R. 485, at para. 8; see also Brown and Evans, at 13:1310; Keyes, at pp. 95-97; *Glykis v. Hydro-Québec*, 2004 SCC 60, [2004] 3 S.C.R. 285, at para. 5; Sullivan, at p. 368; *Legislation Act, 2006*, S.O. 2006, c. 21, Sch. F, s. 64).
3. This inquiry does not involve assessing the policy merits of the regulations to determine whether they are “necessary, wise, or effective in practice” (*Jafari v. Canada (Minister of Employment and Immigration)*, [1995] 2 F.C. 595 (C.A.), at p. 604). As explained in *Ontario Federation of Anglers & Hunters v. Ontario (Ministry of Natural Resources)* (2002), 211 D.L.R. (4th) 741 (Ont. C.A.):

. . . the judicial review of regulations, as opposed to administrative decisions, is usually restricted to the grounds that they are inconsistent with the purpose of the statute or that some condition precedent in the statute has not been observed. The motives for their promulgation are irrelevant. [para. 41]

1. It is not an inquiry into the underlying “political, economic, social or partisan considerations” (*Thorne’s Hardware Ltd. v. The Queen*, [1983] 1 S.C.R. 106, at pp. 112-13). Nor does the *vires* of regulations hinge on whether, in the court’s view, they will actually succeed at achieving the statutory objectives (*CKOY Ltd. v. The Queen*, [1979] 1 S.C.R. 2, at p. 12; see also*Jafari*,at p. 602; Keyes, at p. 266). They must be “irrelevant”, “extraneous” or “completely unrelated” to the statutory purpose to be found to be *ultra vires* on the basis of inconsistency with statutory purpose (*Alaska Trainship Corp. v. Pacific Pilotage Authority*, [1981] 1 S.C.R. 261; *Re Doctors Hospital and Minister of Health* (1976), 12 O.R. (2d) 164 (Div. Ct.); *Shell Canada Products Ltd. v. Vancouver (City)*, [1994] 1 S.C.R. 231, at p. 280; *Jafari*, at p. 604; Brown and Evans, at 15:3261). In effect, although it is possible to strike down regulations as *ultra vires* on this basis, as Dickson J. observed, “it would take an egregious case to warrant such action” (*Thorne’s Hardware*, at p. 111).
2. The grants of authority relevant to the private label regulations are, under the *Drug Interchangeability and Dispensing Fee Act*:

**14.―**(1) The Lieutenant Governor in Council may make regulations,

(a) prescribing conditions to be met by products or by manufacturers of products in order to be designated as interchangeable with other products;

(b) prescribing conditions to be met for a product to continue to be designated as interchangeable;

Under the *Ontario* *Drug Benefit Act*, they are:

**18.―**(1) The Lieutenant Governor in Council may make regulations,

. . .

(b) prescribing conditions to be met for a drug product to be designated as a listed drug product;[[10]](#footnote-10)

(b.1) prescribing conditions to be met for a listed drug product to continue to be designated as a listed drug product;

. . .

(m) respecting any matter considered necessary or advisable to carry out the intent and purposes of this Act.

1. To start the analysis, we must determine the purposes of the enabling statutes.
2. The original legislative intent animating the two *Acts* was to combat high drug prices caused by manufacturers quoting artificially high Formulary prices while providing hidden discounts to pharmacies. When the statutes were first introduced in 1985, the then Minister of Health, the Hon. Murray J. Elston, explained that they were intended to address the problem of “unrealistic” drug pricing:

[The] formulary . . . lists the prices at which government will reimburse pharmacies for drugs dispensed under the program. These formulary prices are based on quotes received from drug manufacturers. They are not set by government.

*Some manufacturers realized that by quoting artificially high prices for the formulary, prices higher than what pharmacies were actually paying for drugs, there was an incentive for pharmacies to purchase their products. Government reimbursements for drugs dispensed under the ODB are, as a result, higher than the cost of many drugs to pharmacies.*

*It can be easily seen how this resulted in excess costs to the Ontario drug benefit plan.* This practice of price spreading, and the fact that it was allowed to continue for so long by the previous government, represents an unnecessary burden on all Ontario taxpayers.

. . . since the Ontario Drug Benefit Formulary is used as a pricing guide for prescription drug sales in the cash market, its artificially high prices have resulted in excess costs for cash customers and for those on other drug plans as well. [Emphasis added.]

(Legislative Assembly, *Hansard – Official Report of Debates*, No. 41, 1st Sess., 33rd Parl., November 7, 1985, p. 1446)

1. In other words, the overarching purpose of the statutory scheme is, as Molloy J. explained, “to control the cost of prescription drugs in Ontario without compromising safety”.
2. The *Acts* and the Regulations under them represent a series of deliberate and aspirationalresponses to what has proven to be a tenacious problem over the past 25 years: manufacturers charging exceptionally high prices for generic drugs flowing not from the actual cost of the drugs, but from the manufacturers’ cost in providing financial incentives to pharmacies to induce them to purchase their products. The government has repeatedly tried to end these hidden benefits. As the legislative history shows, attempts were made to promote transparent pricing and eliminate price inflation along the drug supply chain, all in pursuit of the ultimate objective of lowering drug costs. The legislature also exerted control over the sources of pharmacy revenue, attempting to shift pharmacy revenues away from drug sales and towards the delivery of professional services.  Of necessity, these legislative and regulatory responses have been incremental.
3. Thepurpose of the 2010 Regulations banning private label products was to prevent another possible mechanism for circumventing the ban on the rebates that keptdrug prices inflated. As previously noted, the problem with rebates was that they inflated the Formulary price.  In banning rebates, the expectation was that manufacturers would lower Formulary prices, and that pharmacies would pass these savings on to consumers.  If pharmacies were permitted to create their own affiliated manufacturers whom they controlled, they would be directly involved in setting the Formulary prices and have strong incentives to keep these prices high.  Rather than receiving a rebate financed by inflated drug prices, the pharmacy would share in the manufacturers’ profits from those prices. This was expected to keep the price of drugs to consumers high.
4. These concerns found their way into the June 2010 explanatory letter from the Executive Officer to Sanis. The relevant portions are repeated here for ease of reference:

The purpose of the regulations is to prevent a pharmacy-controlled or related entity purchasing drug products from a person that actually makes the product at lower prices than the drug benefit price on the ODB Formulary without providing any price reduction to patients, insurers, employers, the Government of Ontario, or other payors.

The government’s amendments to Ontario’s drug regulations seek to encourage manufacturers to provide lower prices to Ontario patients. With private label products, the price reductions that Sanis presumably enjoys would not be passed onto end-payors such as government, insurers and patients. Instead, it seems that *profits would be retained within pharmacy-controlled organizations without benefiting consumers. While that would not be a “rebate” as defined in the legislation, it is a similar problem that the provisions against rebates seek to prevent.* [Emphasis added.]

1. The private label Regulations also contribute to the legislative pursuit of transparent drug pricing. The Regulations are consistent with a recommendation in the 2008 Competition Bureau Report that “reimbursement of pharmacy services should be provided separately from reimbursement of drug costs”. The Bureau’s rationale was that provincial governments have difficulty setting appropriate fees for pharmacy services as long as pharmacies continue to receive massive payments from drug manufacturers and can use those revenues to offset under-funding for services and inefficient service delivery (*Benefiting from Generic Drug Competition*,at pp.20-22 and 32). Weaning pharmacies off drug manufacturer revenues and transitioning them to a business model based on reimbursement for providing professional services has therefore been an important strategy pursued in the 2006 and 2010 amendments to the *Acts* and Regulations.
2. The private label Regulations fit into this strategy by ensuring that pharmacies make money exclusively from providing professional health care services, instead of sharing in the revenues of drug manufacturers by setting up their own private label subsidiaries. In this way too, the Regulations correspond to the statutory purpose of reducing drug costs since disentangling the cost of pharmacy services from the cost of drugs puts Ontario in a better position to regulate both.
3. The 2010 private label Regulations were therefore part of the regulatory pursuit of lower prices for generic drugs and are, as a result, consistent with the statutory purpose.
4. Shoppers and Katz argued, however, that the private label Regulations were inconsistent with the statutory purpose because they neither could nor would reduce drug prices. This, with respect, misconstrues the nature of the review exercise. The animating concern of the ban is that private label manufacturers’ affiliation to pharmacies could make them more resistant to Ontario’s efforts to promote lower prices. The Regulationsare therefore connected to the statutory purpose of controlling — and reducing — drug prices. Whether they will ultimately prove to be successful or represent sound economic policy is not the issue. The issue is whether they accord with the purpose of the scheme. In my view, they clearly do.
5. Shoppers and Katz also argued that the private label Regulations are inconsistent with the statutory purpose because they are under-inclusive: they do not prevent a pharmacy from owning a manufacturer who is also the fabricator of the drug. At the moment, this is pure speculation — there are no pharmacies in Ontario which own both the manufacturer and fabricator of a generic drug. It may well be that at some point this will become a corporate structure of concern, but Ontario is not obliged in its regulations to anticipate all potentially problematic scenarios. So long as what it has actually enacted is consistent with the statutory purpose and regulatory scope, Ontariois entitled to address the problem in stages. The ban on private label products is not inconsistent with or extraneous to the statutory purpose simply because it fails to include corporate models that do not currently exist.
6. It bears repeating thatOntario’s totemic struggle to control generic drug prices has been an incremental one, due in part to an evolving awareness of the mechanisms that can lead to high drug prices, and in part to the dynamic nature of the problem: each time the government has introduced new measures, market participants have changed their business practices to obviatethe restrictions and keep prices high.
7. The private label Regulations are part of this incremental regulatory process, tailored to address a proposed business model in which the private label manufacturer is a substitute for a manufacturer which already has its drugs on the market in Ontario. Sanis, for example, proposed to rely on Cobalt and Mylan, two manufacturers who already market generic drugs in Ontario, to fabricate its drugs and to provide it with the groundwork for obtaining regulatory approval. Brent Fraser, the Director of Drug Program Services at the Ministry of Health and Long-Term Care, expressed this very concern about Sanis’ proposal. In his view, Sanis’ intention to rely on other companies like Cobalt or Mylan to develop the products it proposed to sell meant that “the only role of Sanis appears to be to earn a profit for a pharmacy operator over and above the increased dispensing fees, the newly introduced transitional service fees, benefits associated with ordinary commercial terms, and the planned payments for the delivery of professional services”.
8. Shoppers and Katz also argued that the private label Regulations are *ultra vires* because they interfere with commercial rights, prohibit an activity, and discriminate between drug manufacturers, none of which they say is authorised by the grants of regulation-making authority in the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act*. In my view, these arguments cannot succeed.
9. It seems to me somewhat ethereal to speak of a commercial “right” to trade in a market as highly regulated as is the pharmaceutical market in Ontario.Manufacturers have no right to sell drugs in the public market in Ontario unless they are listed in the Formulary, and no right to sell generic drugs at all unless they are designated as interchangeable. Since the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act* give the Lieutenant Governor in Council the authority to set the conditions that a drug must meet in order to be listed in the Formulary and designated as interchangeable, they expressly authorise interference with a manufacturer’s ability to enter and remain in the market.
10. Nor do the private label Regulations contravene the principle that a statutory power to regulate an activity does not include the power to prohibit it. This principle had its origins in *Municipal Corporation of City of* *Toronto v. Virgo*, [1896] A.C. 88 (P.C.), where Lord Davey held that

there is marked distinction to be drawn between the prohibition or prevention of a trade and the regulation or governance of it, and indeed a power to regulate and govern seems to imply the continued existence of that which is to be regulated or governed. [p. 93]

1. Assessing whether a regulation has crossed the line from being a permissible condition into being an impermissible prohibition requires establishing the scope of the activity to be regulated and then determining the extent to which it can continue to be carried on (Keyes, at p. 312). Here, the activity to be regulated is the sale of generic drugs in the private and public markets in Ontario. The private label Regulations do not prohibit manufacturers from selling generic drugs in Ontario’s markets; they restrict market access only if a particular corporate structure is used. That cannot be characterized as a total or near-total ban on selling generic drugs in Ontario.
2. The “discrimination” or unauthorised distinctions argument is similarly without a legal foundation. Regulatory distinctions must be authorised by statute, either expressly or by necessary implication (*Forget v. Quebec (Attorney General)*, [1988] 2 S.C.R. 90, at pp. 106-7). The applicable legislation in this case expressly authorises the making of distinctions between different drug manufacturers. Section 14(1)(a) of the *Drug Interchangeability and Dispensing Fee Act* expressly states that the Lieutenant Governor in Council may make regulations “prescribing conditions to be met by products *or by manufacturers of products* in order to be designated as interchangeable with other products”. Prescribing conditions to be met by drug manufacturers necessarily creates classes of manufacturers who do or do not meet those conditions, and, consequently, to whom the regulations apply differently.
3. Both *Acts* also state that any regulations made under them “may be general or particular in [their] application” (*Ontario Drug Benefit Act*,s. 18(6), *Drug Interchangeability and Dispensing Fee Act*,s. 14(8)). Moreover, both statutes are subject to s. 82 of the *Legislation Act, 2006*, which expressly provides that the power to make regulations includes the power to have them apply differently to different classes:

**82.** (1) A regulation may be general or particular in its application.

(2) The power to make a regulation includes the power to prescribe a class.

(3) For the purposes of subsection (2), a class may be defined,

(a) in terms of any attribute or combination of attributes; or

(b) as consisting of, including or excluding a specified member.

1. The Regulations focus on the sale of drugs by private label manufacturers because those manufacturers and their affiliated pharmacies are the ones consideredto be particularly poised to circumvent the statutory ban on rebates that applies to *all* manufacturers and pharmacies in Ontario. Far from being “discriminatory”, the distinctions they draw flow directly from the statutory purpose and the scope of the mandate.
2. Shoppers and Katz have therefore not, with respect, demonstrated that the Regulations are *ultra vires*.
3. I would dismiss the appeal with costs.

*Appeal dismissed with costs.*

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1. *Health at a Glance 2009: OECD Indicators* (2009) (online), at p. 167. [↑](#footnote-ref-1)
2. Competition Bureau of Canada, *Benefiting from Generic Drug Competition in Canada: The Way Forward* (2008) (online), at p. 7. [↑](#footnote-ref-2)
3. Canadian Institute for Health Information, *National Health Expenditure Trends, 1975 to 2012* (2012), at p. 21. [↑](#footnote-ref-3)
4. *Ontario Drug Benefit Act*, s. 11.5, and O. Reg. 201/96, s. 1; *Drug Interchangeability and Dispensing Fee Act*, s. 12.1, and R.R.O. 1990, Reg. 935, s. 2. [↑](#footnote-ref-4)
5. *Ontario Drug Benefit Act*,s. 0.1. [↑](#footnote-ref-5)
6. O. Reg. 201/96. [↑](#footnote-ref-6)
7. R.R.O. 1990, Reg. 935. [↑](#footnote-ref-7)
8. *Ontario Drug Benefit Act* Regulation, O. Reg. 201/96, s. 12.0.2(1). [↑](#footnote-ref-8)
9. *Drug Interchangeability and Dispensing Fee Act* Regulation, R.R.O. 1990, Reg. 935, s. 9(1). [↑](#footnote-ref-9)
10. A “listed drug product” is a drug listed in the Formulary by the Executive Officer (ss. 1(1), 1.2(2)(a) and 1.3). [↑](#footnote-ref-10)