CITATION: Shoppers Drug Mart Inc. v. Ontario, 2011 ONSC 615
DIVISIONAL COURT FILE NO.: 332/10 and 334/10
DATE: 20110203

ONTARIO

SUPERIOR COURT OF JUSTICE

DIVISIONAL COURT

WHALEN, MOLLOY and SWINTON, JJ.

BETWEEN: Divisional Court File No. 332/10 SHOPPERS DRUG MART INC., SHOPPERS DRUG MART (LONDON) LIMITED and SANIS HEALTH INC. Applicants **– and –** MINISTER OF HEALTH AND LONG-TERM CARE and LIEUTENANT GOVERNOR IN COUNCIL OF ONTARIO Respondents **AND BETWEEN:** Divisional Court File No. 334/10 KATZ GROUP CANADA INC., PHARMA PLUS DRUG MARTS LTD., and PHARMX REXALL DRUG STORES LTD. **– and –** MINISTER OF HEALTH AND LONG-TERM CARE and LIEUTENANT GOVERNOR IN COUNCIL OF ONTARIO Respondents	Mahmud Jamal and Craig Lockwood, for the Applicants Shoppers Drug Mart *et al.* Terrence J. O'Sullivan and Paul Michell, for the Applicants Katz Group *et al.* Kim Twohig, Lise Favreau and Kristin Smith, for the Respondents **HEARD:** October 18, 2010 in Toronto

MOLLOY J.:

REASONS FOR DECISION

A. INTRODUCTION

[1] The applicants in these two parallel applications own and operate hundreds of pharmacies throughout Ontario. They challenge the validity of one aspect of regulations adopted by the Ontario government in 2010 dealing with the sale of prescription drugs in Ontario. The impugned regulations prohibit a "private label" generic drug from being sold on the same basis as other generic drugs. A private label generic drug is identical to other generic drugs, and identical in formula to the brand-name drug for which it seeks to be interchangeable. The only thing that differentiates the private label generic drug from any other generic drug is the nature of the ownership or control of the company that manufactures it. Essentially, private label drug manufacturers are those that are non-arms length from pharmacies.

[2] The applicants either own or control companies that manufacture generic drugs, or plan to do so. In situations in which substitution of generic drugs for brand-name drugs is permitted by law, the applicants seek to use their own private label generic drugs, rather than purchasing those generic drugs from an arms-length third party. The new regulations would effectively prohibit them from doing so.

[3] For the reasons that follow, I find that the regulations in question: (1) fall outside the regulation-making authority delegated by the parent statute, in particular because they purport to prohibit rather than regulate; (2) do not fall within the purpose of the parent statute; and (3) constitute an interference with property and commercial rights that is not expressly authorized by the parent statute. There is some overlap among these concepts; they are not water-tight compartments. The general principle underlying each concept is that executive regulation power must be exercised in conformity with the legislative authority providing for it and any regulations that do not conform have been enacted without jurisdiction. Therefore, whether taken singly, or collectively, the effect of the regulations' failure to meet these criteria is that the regulations are *ultra vires* and of no force and effect.

B. THE LEGISLATIVE REGIME

The Legislative Provisions

[4] In Canada, the approval of a prescription drug by Health Canada is required before that drug can be sold anywhere in the country. That requirement applies to original brand-name drugs (which are initially subject to patent protection), and to subsequent generic versions of those brand-name drugs.[1]

---

[1] *Food and Drugs Act*, R.S.C. 1985, c. F-27

[5] The Ontario government places further controls on the sale of prescription drugs in Ontario through two separate, but interconnected, legislative regimes: the *Ontario Drug Benefit Act* ("ODBA")[2] and the *Drug Interchangeability and Dispensing Fee Act* ("DIDFA")[3].

[6] Under the DIDFA, a generic prescription drug cannot be sold to the public unless it has been approved as "interchangeable" with the relevant brand-name drug by the Executive Officer of the Ministry of Health and Long Term Care ("the Ministry"). Once the interchangeability designation is made, a pharmacist is required to dispense the lower cost interchangeable generic version of the drug to a patient, unless the prescribing physician has specified that no substitutions can be made or the patient agrees to pay the incremental costs of the higher priced brand-name drug.[4] This provision is meant to benefit the public by making lower cost generic drugs available as the norm, subject to the right of the doctor and/or patient to select the more expensive brand-name drug if they choose. The DIDFA also regulates the pricing of interchangeable generic drugs and the dispensing fees that may be charged by pharmacies.

[7] The ODBA governs conditions under which Ontario will pay pharmacies for prescription drugs provided to eligible persons (primarily seniors and persons on social assistance). The ODBA creates the position of Executive Officer, whose responsibilities include deciding which drugs will be listed as benefits under the ODBA and as interchangeable under the DIDFA. The ODBA also provides for the creation and maintenance of a "Formulary" containing a list of all drug products for which Ontario will provide reimbursement and the price Ontario will pay for those drugs.[5]

[8] A generic drug that is not designated as interchangeable under the DIDFA cannot be substituted for a brand-name drug, and is thereby effectively barred from the "private" market. A generic drug that is not listed on the Formulary is excluded from coverage under the ODBA, and is thereby effectively removed from the "public" market.

[9] In *Apotex Inc. v. Ontario (Minister of Health),*[6] the Ontario Court of Appeal held at para. 3 that "[t]he purpose of the system is to allow pharmacists to be able to supply a prescribed drug in the cheapest form possible, both to persons who pay for the drugs themselves and to those who qualify to have the government pay for their drugs." The Court found that the ultimate goal of both pieces of legislation is to make prescription drugs available to the public at lower prices. The Court held (at para. 5):

> Each Act plays a distinct role within the scheme, the ultimate goal of which is to make generic drugs available to eligible persons and the rest of the public at low prices. The DIDFA dictates how drug products in the Formulary are deemed to be interchangeable with one another, while the OBDA dictates how drug products

---

[2] R.S.O. 1990, c. O.10.
[3] R.S.O. 1990, c. P. 23.
[4] DIDFA, ss. 4, 5.
[5] ODBA, ss. 1.1, 1.2.
[6] *Apotex Inc. v. Ontario (Minister of Health)* (2004), 73 O.R. (3d) 1. (C.A.)

are listed in the Formulary as products that may be supplied to eligible persons. Both Acts include conditions with respect to the pricing of generic drugs.

[10] Under both Acts, the Lieutenant Governor in Council is given regulation-making authority. Under the DIDFA, that authority is found in s. 14(1), the relevant portion of which provides:

> 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;
>
> . . .
>
> (d) defining any word or expression used in this Act but not defined in this Act.

[11] Similar regulation-making powers are contained in s. 18(1) of the ODBA:

> 18. (1) The Lieutenant Governor in Council may make regulations,
>
> (0.a) defining any word or expression used in this Act but not defined in this Act;
>
> . . .
>
> (b) prescribing conditions to be met for a drug product to be designated as a listed drug product;
>
> (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.

Pricing Controls Prior to 2006

[12] Prior to 2006, a Regulation under the ODBA fixed the price Ontario would pay for generic drugs based on a "70/90 rule". Subject to some exceptions, this meant that the first generic drug to apply for listing in the Formulary would be priced at 70% of the price of the brand-name drug. The next drug to be listed would be priced at 90% of the price of the first generic drug listed, which typically would result in the manufacturer of that first drug dropping its price to be competitive. Thus, the effective price for all generic drugs listed would be 63% of

the comparable brand-name drug. Manufacturers of generic drugs challenged the validity of these provisions, but they were found to be *intra vires* by the Ontario Court of Appeal.[7]

[13] Prior to 2006, the DIDFA stipulated that a pharmacy providing an interchangeable generic drug must charge the lowest price for that drug that was in its inventory. Since most pharmacies would serve eligible persons under the ODBA, they would have in their inventory a product that reflected the price Ontario would pay under the ODBA. Therefore, effectively, generic drugs were provided to consumers generally at the same price the government paid.

[14] During this time period, the ODBA and its Regulation provided that for drugs dispensed under the ODBA, the pharmacies were entitled to receive: (a) the price of the drug set out in the Formulary; (b) a dispensing fee fixed at $6.54; and (c) a mark-up of 10%. Under this regime, manufacturers supplying generic drugs to pharmacies sought to gain a competitive advantage by providing promotional rebates (in the form of cash or other incentives) to pharmacies for buying that manufacturer's product. Generic drug manufacturers competed with each other in respect of the amount of rebates they would provide to pharmacies in exchange for their business. These cost savings by pharmacies were not passed on to the consumer as pharmacies continued to charge the price fixed by the Formulary and under the ODBA. Studies showed that the cost of generic drugs in Canada at this time was higher than in other countries, at least in part because of the payment of rebates to pharmacies.

Changes to Pricing Controls in 2006

[15] In 2006, significant amendments were made to the ODBA and the DIDFA. In the public market, the price Ontario would pay for generic drugs was reduced from 63% to 50% of the price of the brand-name drug. Dispensing fees were raised to $7.00, but the permissible mark-up on drugs was reduced from 10% to 8%. In the private market, pricing restrictions were removed and the price chargeable for an interchangeable product under the DIDFA was no longer tied to what was paid under the ODBA. In both markets, rebates were banned, subject to an exception that permitted pharmacies to receive "professional allowances" from drug manufacturers to be used for patient care purposes.

[16] After the 2006 amendments came into force, the prices of generic drugs continued to be higher than international averages, and the amounts pharmacies received for professional allowances were very high despite the ban on rebates. In November 2008, the Competition Bureau of Canada published a report in which it found that the rebates paid to pharmacies accounted for at least 40% of the generic drug costs borne by public and private payers. The report noted that the use of rebates as a competitive practice was viewed as artificially driving up the cost of generic drugs for payers. The study found that if rebates were not paid to pharmacies, the price of drugs that is reimbursed to pharmacies and paid by patients, government, and private insurers could be lower. It recommended that provincial drug plans should, *inter alia*, reimburse pharmacy services such as dispensing and patient services separately from drug costs.

---

[7] *Apotex, supra.*

[17] It was in response to concerns such as these that Ontario enacted further amendments in 2010.

The 2010 Amendments

[18] The proposed amendments to the drug scheme regulations were introduced along with the 2010 budget bill in March 2010. The amendment to the ODBA regulation was proclaimed in force on July 1, 2010 and the amendment to the DIDFA regulation will come into force as of April 1, 2013.

[19] The combined effect of the 2010 regulations will eliminate "professional allowances" as permitted rebates from manufacturers. This was done immediately in the public sector under the ODBA, and is to be phased in gradually in the private market with elimination by April 2013. The price Ontario will pay for generic drugs was reduced to 25% of the brand-name drug. In the private sector, prices for generic drugs were set at 50% of the brand-name price effective July 1, 2010, with gradual further reductions until April 2013 when sales to the general public will effectively be pegged at the same price paid by Ontario under the ODBA. The mark-up remains at 8%, but dispensing fees were increased and funding of $100 million was allocated for the development of professional services. The Executive Officer will also pay pharmacies an additional fee on most claims under the ODBA until March 31, 2013, when it is expected that a fee schedule for professional services will have been developed.

[20] None of these provisions with respect to pricing, rebates or professional allowances are challenged.

The Private Label Product ("PLP") Provisions

[21] Along with the provisions referred to above, the 2010 amendments introduced new regulations dealing for the first time with private label products. Parallel amendments were added to both the DIDFA Regulation and the ODBA Regulation. A private label product ("PLP") is defined in both regulations in the same terms, as follows:[8]

> "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,

---

[8] O. Reg. 201/96, made under the ODBA, s. 12.0.2(2); R.R.O. 1990, Reg. 935, made under the DIDFA, s. 9(2).

> (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 of 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.

[22] The use of the word "manufacturer" in this context is somewhat confusing and it is not defined in either of the Ontario statutes. However, all of the parties agree that "manufacturer" and "fabricator" are terms of art in the industry and that they are to be given the definitions set out in the federal legislation. In the federal *Food and Drugs Act Regulations*, "manufacturer" and "distributor" have the same definition—a "person ... who under their own name ... sells a food or drug."[9] In that same Regulation "fabricate" is defined to mean "prepare and preserve a drug for the purposes of sale."[10] Thus, a manufacturer is an entity that sells a drug under its own label, regardless of whether it actually fabricates that drug itself, or hires some other company to do that.

[23] In the context of this case, the applicant Sanis Health Inc. is a corporation within the Shoppers Drug Mart group of companies. Sanis is a licensed manufacturer regulated by Health Canada and it provides generic drugs under its own label to Shoppers Drug Mart pharmacies. Sanis does not fabricate those drugs itself; the drugs are fabricated for Sanis by another company under contract. Because Sanis is a "manufacturer" that does not itself fabricate drugs, and because it is supplying drugs to a company that franchises pharmacies, Sanis label generic drugs are defined to be "private label products."

[24] The Katz group does not yet have such an arrangement, but is in the process of setting one up. The applicants filed affidavit evidence from an expert that this sort of arrangement is common in the drug industry.[11]

[25] The implications of falling within the PLP provisions are significant. Section 12.0.2(1) of the ODBA Regulation provides that a private label product "shall not be designated as a listed drug product." Similarly, s. 9(1) of the DIDFA Regulation provides that a private label drug "shall not be designated as interchangeable." For all practical purposes this means that Sanis label generic drugs cannot be sold in the public or private market in Ontario.

C. STANDARD OF REVIEW

[26] In *United Taxi Drivers' Fellowship of Southern Alberta v. Calgary (City)*, the Supreme Court of Canada held that a question as to whether a regulation is *ultra vires* its enabling statute

---

[9] *Food and Drugs Regulations*, C.R.C. c. 870, s. A.01.010.
[10] *Ibid.*, s. C.01A.001.
[11] Affidavit of Russell Cohen sworn September 15, 2010, at paras 3-6, Supplementary Application Record, pp. 182-184.

"will always be reviewed on a standard of correctness".[12] In their written facta, all parties acknowledged that the correctness standard applies.

[27] However, in oral argument Ms. Twohig (for the respondent) qualified that position somewhat by submitting that the standard is correctness, but "in a deferential manner." She relied in that regard on *United Taxi Drivers* as well as two decisions of the Ontario Court of Appeal in separate *Apotex*[13] cases and the Federal Court of Appeal decision in *Sunshine Village v. Canada (Parks)*.[14]

[28] I do not see those cases as altering the correctness standard of review, although they do recognize that the proper interpretation of statutes, which will almost always be part of an *ultra vires* analysis, involves some degree of deference to matters of government policy.

[29] Thus, in *United Taxi Drivers*, the Supreme Court of Canada, in considering whether a municipal bylaw imposing a freeze on the issuance of taxi plate licenses was *ultra vires,* was clear that the correctness standard applied. The Court held that there was no need on such issues to even inquire into the applicable standard of review as those issues only applied where the municipality was exercising an adjudicative or policy-making function. The Court then went on to consider the well-established principles of statutory interpretation, including that statutes are to be given a fair, large and liberal construction that best assures the attainment of their objects and that a contextual approach requires that the words of an Act "be read in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament".[15]

[30] Similarly, at para. 10 of its decision in *Sunshine Village*, the Federal Court of Appeal accepted the correctness standard, citing *United Taxi Drivers*. At para. 22 of the decision, in dealing with whether by-laws discriminating between parties were authorized, Rothstein J.A. mentioned that courts approach such reviews "in a deferential manner", but immediately followed that observation by stating, "That is simply a matter of interpreting in context, the words Parliament has used in accordance with their ordinary and grammatical meaning."

[31] The Ontario Court of Appeal also does not depart from the correctness standard in the *Apotex* decisions cited by the respondent. In its 2007 decision, the Court's reference to deference to the legislature was in the context of interpreting the scope of delegated powers within the context of the underlying purpose of the legislation. The 2004 *Apotex* decision involved a challenge to the regulatory requirements at that time imposing a price freeze on generic drugs and fixing the pricing of generic drugs as a percentage of the equivalent brand-name drug. The Court of Appeal found that these provisions were authorized by the enabling

---

[12] *United Taxi Drivers' Fellowship v. Calgary (City)*, [2004] 1 S.C.R. 485, at para. 5.
[13] *Apotex Inc. v. Ontario (Lieutenant Governor in Council)* (2007), 229 O.A.C. 11 (C.A.), at paras. 35 and 38; and *Apotex Inc. v. Ontario (Minister of Health)* (2004), 73 O.R. (3d) 1 (C.A.), at paras. 37 and 39.
[14] *Sunshine Village Corp. v. Canada (Parks)*, [2004] 3 F.C.R. 600 (F.C.A.), at para. 22.
[15] *United Taxi Drivers, supra*, at para. 8, citing E. A. Driedger, *Construction of Statutes*, 2nd ed. (Toronto: Butterworths, 1983), at 87, and *Bell ExpressVu Limited Partnership v. Rex*, [2002] 2 S.C.R. 559, 2002 SCC 42, at para. 26.

legislation, fell within the purpose of the ODBA and the DIDFA, and were therefore *intra vires*. The Court then considered arguments by the applicants based on the effectiveness of the government policy in light of affidavit evidence from experts that the government policy may have the effect of increasing the cost of generic drugs rather than lowering them. It was in that context that the Court, at paras. 37 and 39, declined to inquire into the "correctness of the government's decisions and policies."

[32] Accordingly, in approaching this issue, the ODBA and the DIDFA must be given a broad and liberal interpretation, consistent with their purpose. The approach must be contextual and an interpretation that is consistent with the intention of the legislature must be preferred. However, regulations are a form of delegated legislation. They owe their existence and authority to primary legislation, in this case, either the ODBA or the DIDFA. The executive branch of government has no inherent legislative power; it has only that power that is delegated to it by statute. Therefore, the scope of the regulation-making power is limited by the scope of the power delegated under the legislation. Once the purpose of the legislation is established, and its language is interpreted consistently with that purpose, the regulations are required to be authorized by the enabling statute and to be consistent with that purpose. This is a pure question of law. The Lieutenant Governor in Council is either empowered to enact the regulation or he is not. If the regulations do not meet these criteria for validity, then they are *ultra vires* and cannot stand. There is not, at that stage, any question of deference.

D. BEYOND THE SCOPE OF THE REGULATION-MAKING AUTHORITY

[33] In his definitive text on administrative law, Professor David Mullan states, "Subordinate legislation which is beyond the scope of the empowering sections of the principal Act is invalid."[16] The first task, therefore, is to consider the scope of the regulation-making power conferred by the enabling statutes. Those powers are set out in s. 14 of the DIDFA and s. 18 of the ODBA (see paras. 10 and 11 above).

[34] The impugned section of the DIDFA Regulation provides that private label products "shall not be designated as interchangeable."

[35] Under s. 14(1)(d) of DIDFA, regulations are permitted for the purpose of defining a word used in the Act. Although private label product is defined within the impugned section of the Regulation, it is not a term used elsewhere in the Regulations or the Act. Further, this enabling provision would not authorize prohibiting private label drugs from being interchangeable.

[36] If the Regulation is authorized at all, it can only be pursuant to ss. 14(1) (a) or (b), which authorize regulations "prescribing conditions to be met" in order for a product to be designated, and continue to be designated, as interchangeable.

[37] On a plain reading of s. 9 of the DIDFA Regulation, it is clear that it does not prescribe any condition to be met by either the manufacturer or the product in this situation. If the

---

[16] *Administrative Law*, 3rd ed. (Toronto: Carswell, 1996) at §512. See also Ruth Sullivan, *Sullivan on the Construction of Statutes*, 5th ed. (Markham: LexisNexis, 2008) at 456.

manufacturer falls within the definition of "private label product", that is the end of the matter. There is nothing that can be done with the product to bring it into compliance. Private label products are simply prohibited from being designated as interchangeable because of the connection between the manufacturer and the pharmacy. This is a "need not apply" type of provision.

[38] The same reasoning applies to the ODBA. The impugned section of the ODBA Regulation provides that private label products "shall not be designated as a listed drug product." Sections 18(1) (b) and (b.1) authorize regulations "prescribing conditions to be met for a drug product to be designated" in virtually the same language as the equivalent sections of the DIDFA. Again, the impugned provision does not prescribe conditions to be met; it simply provides that private label drugs shall not be listed.

[39] It is a settled legal principle that a delegated authority to impose conditions on an activity does not authorize a prohibition of the activity. Professor Mullan writes in *Administrative Law:*[17]

> [A]uthority to regulate does not include authority to prohibit absolutely or to deregulate entirely. Even if the subordinate legislation is regulatory in form, it is invalid if it is prohibitory in substance.

[40] In *Edwards v. Faraday (Township)*,[18] the applicants operated a large dog breeding business, which included 150 adult dogs. The municipality passed a by-law imposing "conditions" on the licensing of dog kennels, including a limit of 35 dogs and a requirement of $2 million in insurance. The court referred to established authorities that the power to regulate does not give the power to prohibit. Although the licensing by-law in that case was expressed as imposing conditions for licensing, those conditions were found to be so onerous that the court concluded at para. 58 that the by-law was in pith and substance "prohibitory rather than regulatory" and therefore *ultra vires.*

[41] The Federal Court of Appeal took a similar approach in *Anderson v. Canada (Attorney General),*[19] a case involving an unemployment insurance regulation that effectively prohibited school teachers from receiving benefits during July and August. The enabling statute authorized regulations "imposing additional conditions and terms with respect to the payment and receipt of benefit" in respect of occupations that by custom have a repetitive annual period during which no work is performed. Although the regulation in question was worded as if it was imposing conditions on the qualification for benefits, the Court found that its effect was to prohibit payment of the benefit and this was fatal to its validity.

---

[17] Mullan, *ibid.*, at §512; See also Donald J.M. Brown, Q.C. and Hon. John M. Evans, *Judicial Review of Administrative Action in Canada*, looseleaf (Toronto: Canvasback, 2010), §15.3263, at pp. 15-54 to 15-92.

[18] *Edwards v. Faraday (Township)* (2006), 147 A.C.W.S. (3d) 1070 (Ont. S.C.).

[19] *Anderson v. Canada (Attorney General,* [1983] 2 F.C. 437 (C.A.). See also *Petts v. Canada (Unemployment Insurance Act, Umpire)*, [1974] 2 F.C. 225 (C.A.), an earlier case dealing with the same point and the same legislation, but with a differently worded regulation.

[42] Prior to the commencement of this litigation, the Ontario government itself described the PFP provisions as being prohibitions. The government established a website providing information to the public about the changes to the legislation. In one of the government's publications on the website (posted on April 7, 2010), the government stated that the proposed changes would "[n]ot allow private label generics." In a similar publication (posted on June 7, 2010), the government stated, "Private label generic products are prohibited in both public and private markets".[20] Indeed, the respondents' own witness described the regulations as a "prohibition of private label products" in his affidavit filed on this application.[21]

[43] How the government itself characterized the impugned sections of the Regulations is, of course, not determinative of whether they are in pith and substance prohibitions rather than the imposition of conditions. Nevertheless, it is interesting to note that most, if not all, cases involving this distinction between prohibition and regulation involve language that on its face appears to impose conditions, but which in effect constitutes a prohibition. The language in this case, however, is prohibitory on its face.

[44] It is also interesting to compare the language used in s. 9 of the DIDFA Regulation (dealing with private label products) and the language of s. 6 of that Regulation (dealing with conditions for designation). Section 9 provides that private label products "shall not be designated." By way of contrast, section 6(1) states as follows:

> **6.** (1) It is a condition for each strength and dosage form of a drug product to be designated as interchangeable with other products that the manufacturer of the drug product submit to the executive officer,
>
> > (a) evidence that Health Canada has approved the product for sale in Canada, a copy of the product's drug notification form issued by Health Canada and, subject to subsection (2), a copy of the product monograph approved by Health Canada;
> >
> > (b) a letter authorizing the executive officer to gain access to all information with respect to the product in the possession of Health Canada, the Patented Medicine Prices Review Board established under section 91 of the *Patent Act* (Canada), the government of any province or territory in Canada or the Canadian Agency for Drugs and Technologies in Health and authorizing the executive officer to disclose any information with respect to the product in the possession of the Ministry to Health Canada, the Patented Medicine Prices Review Board, the government of a province or territory in Canada or the Canadian Agency for Drugs and Technologies in Health;
> >
> > (c) documentation disclosing the product's master formulation;

---

[20] Application Record, at pp. 286 and 241.
[21] Affidavit of Brent Fraser, sworn September 10, 2010, at para. 67, Responding Record, pp. 1-24.

> (d) the proposed drug benefit price of the product, where it is proposed that the product be designated as a listed drug product under the *Ontario Drug Benefit Act*, and a proposed manufacturer's list price where it is not proposed that the product be so designated;
>
> (d.1) Revoked: O. Reg. 496/00, s. 1 (4).
>
> (e) evidence that the manufacturer is able to supply the product at the proposed drug benefit price in a quantity sufficient to meet the anticipated demand for the product where it is proposed that the product be designated as a listed drug product under the *Ontario Drug Benefit Act*;
>
> (f) certification in writing that no rebate as defined in subsection 12.1 (14) of the Act has been provided to a person listed in subsection 12.1 (1) of the Act with respect to the product contrary to the Act since Health Canada approved the product for sale in Canada;
>
> (g) Revoked: O. Reg. 496/00, s. 1 (5).
>
> (h) comparative bioavailability studies on humans, comparative clinical studies on humans, or both, or other in vivo studies that will show the interchangeability of the product with the original product.
>
> [Emphasis added.]

[45] Section 8 of the DIDFA Regulation, dealing with conditions for the continuation of the designation is similarly worded. It starts by stating that "the following conditions must be met" and then lists a series of conditions which, if satisfied, will permit the designation to be continued.

[46] This type of language, listing conditions to be satisfied, stands in stark contrast to s. 9, which merely provides that private label drugs "shall not" be designated.

[47] The language used in the ODBA Regulation is also illustrative. For example, s. 11 begins by stating that a drug shall not be listed "unless the manufacturer submits the information required under section 12 and the following conditions are met" and then provides a long list of conditions, including alternatives to some of the conditions, which need to be satisfied before the drug will be listed in the Formulary. Likewise, s. 12.1 provides that "the following conditions must be met" for a drug to continue to be listed, and then sets out a list of conditions to be satisfied.

[48] Again, this language is quite different from s. 12.0.2 which deals with private label products and which simply states that they "shall not be designated as a listed product."

[49] It is a basic principle of statutory construction that words used in legislation are to be given their plain and ordinary meaning. The language used in the impugned Regulations in this case, in its plain and grammatical sense, is prohibitory. Further, it is clear that the intention of

the government was to prohibit certain private label generic products altogether based on the corporate relationships of the manufacturer, fabricator and customer. The government did not intend to impose conditions that, if met, would enable the generic drugs supplied by Sanis, for example, to be listed in the Formulary.

[50] Further, I find that in pith and substance the provisions are prohibitory. They do not purport to impose conditions upon private label products, the compliance with which will result in their being listed. On the contrary, the Regulations set out to, and do, ban private label generic drugs from the public and private markets, based on the corporate ownership of the manufacturer.

[51] The statute does not give the Lieutenant Governor in Council the power to make regulations banning classes of persons from supplying generic drugs in the public or private market. There is only a power to regulate, not a power to prohibit. Accordingly, in my opinion, the Regulations are *ultra vires.*

[52] I have considered as well whether the PLP provisions could be *intra vires* based on the regulation-making power in s. 18(1)(m) of the ODBA, which authorizes the making of regulations "respecting any matter considered necessary or advisable to carry out the intent and purposes of this Act." In my view, this broadly worded provision cannot save the PLP provisions for two reasons: (1) because the section is overly broad and cannot be interpreted as giving the government a "blank cheque" to make any regulations it considers advisable; and (2) because in any event the PLP provisions go beyond the purpose of the legislation, as I will develop more fully in the next section of these Reasons.

[53] As to the first point, a similar issue arose in *ATCO Gas & Pipelines Ltd. v. Alberta (Energy & Utilities Board).*[22] In that case, the Supreme Court of Canada considered a power granted by statute to the Alberta Energy and Utilities Board to "impose any condition to any order so long as the condition is necessary in the public interest." The Court held that this could not be construed to give the Board complete discretion. Bastarache J. stated, at para. 46:

> ... These provisions on their own are vague and open-ended. It would be absurd to allow the Board an unfettered discretion to attach any condition it wishes to an order it makes. Furthermore, the concept of "public interest" found in s. 15(3) is very wide and elastic; the Board cannot be given total discretion over its limitations.

[54] Likewise, in *Bomberry v. Ontario (Minister of Revenue)*[23] the government sought by regulation to impose a tobacco quota on Indian retailers selling tobacco products on reserves as a means of protecting its revenue stream from taxes on tobacco. The regulation-making powers under the *Tobacco Tax Act* included the power to regulate "any matter necessary or advisable to

---

[22] *ATCO Gas & Pipelines Ltd. v. Alberta (Energy & Utilities Board,* [2006] 1 S.C.R. 140, 2006 SCC 4 at para. 46.

[23] (1989), 60 D.L.R. (4th) 526.

carry out effectively the intent and purposes of this Act."[24] The Divisional Court held that this general power was inadequate to authorize a specific interference with the right of trade, such as the quota in question. The Court held, at p. 542:

> While the legislature conferred a general power to pass regulations to authorize the collection of tax imposed by the Act and to do things necessarily incidental to carrying out the powers granted by the Act, the legislature did not thereby write the Minister or the Director a blank cheque.
>
> Before an impugned power may be said to be necessarily incidental to a statutory power, the statutory power must be clearly identified to which the impugned power is necessarily incidental. The incidental power must have some peg to hang on. There is no provision in the Act which can support a quota as a necessarily incident power. The over-all purpose of the Act is to collect tax from consumers through a system of wholesale dealers. It is a very large step from a tax on consumers to a quota system for Indian retailers.
>
> If this enforcement scheme can be considered as necessarily incidental to the Act without any specific statutory authority or any specific regulation, then virtually any power could be considered necessarily incidental and there would be no need to have any regulation at all.
>
> It would require much more explicit language to authorize the restrictions on the freedom of the Indian retailers imposed by the quota system.

[55] In my view, the general power in s. 18(1)(m) of the ODBA to make any regulation thought advisable to advance the purposes of the legislation is not sufficiently specific to ban a whole category of drug manufacturers from the market based solely on their corporate structure and relationship to a pharmacy. The power is simply too vague to support such a prohibition. In any event, for the reasons that follow, the PLP provisions are not consistent with the purposes of the legislation and cannot render the provisions *intra vires* for that reason as well.

E. NOT CONSISTENT WITH PURPOSE OF OBDA AND DIDFA

Applicable Legal Principles

[56] A regulation that is not consistent with the purposes and objects of its parent statute is *ultra vires*. Even the broadest of regulation-making powers are constrained by this principle – they must be exercised in a manner consistent with the purpose of the enabling statute, or they will be invalid. This is a concept so fundamental as to be considered part of the rule of law.[25]

---

[24] *Tobacco Tax Act*, R.S.O. 1980, c. 502, s. 28(1)(o).

[25] Mullan, *supra* note 16, at §512; Brown and Evans, *supra* note 17, at §15:3261, pp. 15-54 to 15-57; *ATCO Gas, supra*, at paras. 7 and 46; *Roncarelli v. Duplessis*, [1959] S.C.R. 121 at 140; *Montréal (City) v. Montreal Port Authority*, [2010] 1 S.C.R. 427, 2010 SCC 14, at para. 33.

[57] In *Re Doctors Hospital and Minister of Health,*[26] the Divisional Court considered the validity of Orders in Council, by which the government purported to close several public hospitals for budgetary reasons. The government relied on a provision of the *Public Hospitals Act* which stated that any approval given under the Act could be revoked by the Lieutenant Governor in Council.[27] The Divisional Court held that the parent statute was regulatory in nature and was concerned primarily with the staffing, management and operation of public hospitals. Since the Act did not contemplate exercising financial or budgetary control over hospitals, the Court held that exercising the power to revoke approval for financial reasons was extraneous to the purpose of the statute and therefore invalid.

[58] To similar effect is the decision of the Divisional Court in *Szmuilowicz v. Ontario (Minister of Health),*[28] in which the issue was a regulation enacted under the *Medicine Act, 1991*[29] defining "professional misconduct" by doctors to include charging patients an annual block fee for uninsured services. The purpose of the *Medicine Act* was to regulate the professional conduct of doctors, whereas the purpose of the regulation was related to OHIP and concerns about over-billing. Rosenberg J. held, at p. 223:

> The authority given to the Lieutenant Governor in Council is to define "professional misconduct". Accordingly the statutory purpose for which the regulation must adhere is narrowed. Whether or not the regulation is made with the best of intentions, a departure from the purpose of the *Medicine Act* is objectionable and subject to review by the court. In this case the regulation was made for a purpose extraneous to the purpose of the *Medicine Act* but for the purpose of assuring accessibility and preventing so-called abuses of "extra-billing". The definition of "professional misconduct" cannot be distorted to accomplish purposes outside the purpose of the *Medicine Act* ...

[59] Thus, the analysis on this issue must first inquire into the purposes and objects of the ODBA and the DIDFA, and then determine whether the PLP provisions fall within those purposes, or whether they were enacted for a purpose extraneous to the purpose of the parent legislation.

The Purpose of the Parent Statutes

[60] The Supreme Court of Canada held in *R. v. Gladue*[30] that the purpose of a statute is to be determined on the basis of intrinsic and admissible extrinsic sources regarding the statute's legislative history and the context of its enactment. Obviously, the content of the statute itself is also a primary source in determining its purpose.

---

[26] *Re Doctors Hospital and Minister of Health* (1976), 12 O.R. (2d) 164 (Div.Ct.)
[27] R.S.O. 1970, c. 378, s. 4(5).
[28] *Szmuilowicz v. Ontario (Minister of Health)* (1995), 24 O.R. (3d) 204 (Div.Ct.).
[29] S.O. 1991, c. 30.
[30] *R. v. Gladue,* [1999] 1 S.C.R. 688, at para. 25.

[61] The ODBA contains an opening provision, similar to a preamble, setting out the principles underlying the Act. While these are not explicit statements as to the purpose of the legislation, they do inform that analysis. Section 0.1 provides:

> 0.1 In this Act, the following principles are recognized:
>
> 1. The public drug system aims to meet the needs of Ontarians, as patients, consumers and taxpayers.
>
> 2. The public drug system aims to involve consumers and patients in a meaningful way.
>
> 3. The public drug system aims to operate transparently to the extent possible for all persons with an interest in the system, including, without being limited to, patients, health care practitioners, consumers, manufacturers, wholesalers and pharmacies.
>
> 4. The public drug system aims to consistently achieve value-for-money and ensure the best use of resources at every level of the system.
>
> 5. Funding decisions for drugs are to be made on the best clinical and economic evidence available, and will be openly communicated in as timely a manner as possible.

[62] The DIDFA does not have an equivalent provision. However, the original long title of the Act – *An Act to Provide for the Protection of the Public in respect of the Cost of Certain Prescription Drugs* – provides some indication of its underlying purpose.

[63] The ODBA and the DIDFA were enacted together in 1986 as companion statutes.[31] At first reading, on November 7, 1985, the Minister of Health, the Hon. Murray Elston stated:[32]

> Today I will introduce two bills into this House, bills which will ensure sound management of the Ontario drug benefit plan, protect all consumers of prescription drugs in Ontario, and re-establish public confidence in our retail drug industry. ...
>
> The Ontario Drug Benefit Act, for the first time, gives government the legislative authority to manage the Ontario drug benefit plan.
>
> The second bill I am introducing today, the Prescription Drug Cost Regulation Act, is consumer protection legislation to ensure that high-quality, low-cost drugs are available and accessible to the Ontario public.

---

[31] The ODBA was enacted by Bill 54, S.O. 1986, c. 27. The DIDFA, originally titled the *Prescription Drug Cost Regulation Act, 1986*, was enacted by Bill 55, S.O. 1986, c. 28.

[32] Ontario, Legislative Assembly, *Official Report of Debates (Hansard)* (07 November 1985) at 1446-1447 (Hon. Mr. Elston, Minister of Health).

> Under the first bill, the Ontario Drug Benefit Act, government will be given legislative authority to determine what drugs are to be included in the Ontario drug benefit plan, who is eligible to receive drug benefits, and the prices that government will pay for drugs listed in the ODB Formulary. ...
>
> The second bill, the Prescription Drug Cost Regulation Act, governs all drug purchases made in Ontario, whether under the ODB plan, a private drug plan or in the cash market.
>
> Under this act, the government can designate which drugs are interchangeable. These decisions will be based on the recommendations of the Drug Quality and Therapeutics Committee, an external advisory group to the Minister of Health, composed of physicians, pharmacists and pharmacologists. Except where a physician has written specifically, "No substitution," pharmacists will have to inform customers about their right to request an interchangeable drug. Pharmacists will then be required to fill prescriptions according to the customer's choice. ...
>
> The two acts are complementary in that government use of public funds will be more properly controlled and consumer interests in the marketplace better protected. If senior citizens and other eligible people are to continue receiving drugs at no charge, Ontario drug benefit costs must be brought under control and the program more effectively managed.

[64] There have been a number of judicial determinations as to the purpose of these two statutes. For example, in 2007 in *Apotex Inc. v. Ontario (Lieutenant Governor in Council)*, *supra*, the Court held at paras. 6-7:

> In Ontario, the D.I.D.F.A. ensures that a consumer is offered the lowest priced drug by stipulating generic brands that are "interchangeable" in terms of safety and effectiveness to the brand name drug that may have been prescribed. Under the D.I.D.F.A., a pharmacist is required to dispense the lowest priced interchangeable brand of a prescribed drug unless the doctor specifies "no substitution" or the patient requests a higher price brand. The provincial Minister of Health publishes a schedule for designated interchangeable drug products known as the Comparative Drug Index ("CDI").
>
> Under a separate provincial regime, certain eligible individuals are provided with prescription drugs at no cost. This regime is governed by the *Ontario Drug Benefit Act*, R.S.O. 1990. c. O-10 ("O.D.B.A."). The O.D.B.A. defines categories of persons who are entitled to receive their prescription drugs free of charge and regulates the system by which pharmacists dispensing drugs to such persons are reimbursed by the government. The Ontario Drug Benefit Formulary (the "Formulary") lists the drugs available to eligible persons free of charge under the O.D.B.A.

[Emphasis added.]

[65] Similarly, as I noted in para. 9 above, the Court of Appeal in another *Apotex* decision described the "ultimate goal" of the legislation as being "to make generic drugs available to eligible persons and the rest of the public at low prices."[33]

[66] In my view, it is clear from these sources, and from the content of the two statutes, that the purpose and object of this legislation is to control the cost of prescription drugs in Ontario without compromising safety. There is an additional purpose to further that end by ensuring that safe and effective generic drugs are provided at the lowest price possible. The legislation seeks to benefit both the general consumer (by controlling the price at which pharmacies sell prescription drugs to the public) and the financially disadvantaged (by keeping government drug costs low so that government can continue to provide drug benefits to seniors and those on social assistance).

The Private Label Ban is not Consistent with the Purpose of the Legislation

[67] The next step in the analysis is to determine whether the regulations now being challenged can be said to fall within the purpose and object of the legislation.

[68] The PLP provisions were introduced at the same time as other amendments to the regulations that clearly are related to lowering the cost of generic drugs. It is therefore important to scrutinize government studies, policy statements and pronouncements as to the purpose of the amendments to determine if the justifications or explanations offered relate at all to the PLP provisions, or if they refer only to the other amendments. In fact, the respondents have not presented any such material that refers directly to the PLP provisions, other than to simply state that private label products will be prohibited, nor are there any studies indicating a problem with pharmacies having private label drugs. Nothing in the documentation produced provides any insight into why banning private label products would advance the purpose of the legislation.

[69] Some insight can, however, be gleaned from the history of the government's dealings with Sanis prior to its announcement of the 2010 drug reform proposals. On February 3, 2010, Sanis applied to the Ontario Ministry of Health to have its generic version of Azithromycin (an antibiotic) listed on the Formulary. Between February 26 and May 4, Sanis applied to list a further 19 generic drugs. On February 17, 2010, the Ministry's Executive Officer asked Sanis for information about its corporate structure, business model and commercial relationships, which information was provided on May 4, 2010.

---

[33] *Apotex Inc. v. Ontario (Minister of Health)* (2004), 73 O.R. (3d) 1 (C.A.), at para 5. See also *Ontario (Minister of Health) v. Apotex Inc.* (2002), 60 O.R. (3d) 209 (C.A.), at paras. 5-12; *Apotex Inc. v. Ontario (Health and Long-Term Care)* (2006), 219 O.A.C. 221, at para. 13 (Div. Ct.); *Apotex Inc. v. Ontario (Public Drug Programs)* (2009), 315 D.L.R. (4th) 344, at para. 61 (Ont. Div. Ct.).

[70] By letter dated June 8, 2010, the Executive Officer refused to approve Sanis' drugs for listing on the Formulary. She referred to the fact that the Ministry had recently posted notice of proposed regulations and that Sanis drugs would constitute "private label products" because it did not fabricate the drugs itself and did not have an arms length relationship with Shoppers Drug Mart. The Executive Officer spoke directly about the purpose of the regulations, stating:

> 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 Drug 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 [*sic*] 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 the Products in preference to others, which raised the potential for conflict of interest. [Emphasis added.]

[71] Thus, two justifications were offered for the regulation banning private label products: (1) to protect against a potential conflict of interest; and (2) to prevent profits being retained within pharmacy-controlled organizations without benefiting customers. This latter concern is described as being something "similar" to a rebate, even though the government acknowledges that it is not actually a rebate.

[72] Any concern about possible conflict of interest is clearly outside the purview of this legislation. The professional ethics of pharmacists and the regulation of pharmacies are the object and purpose of other legislation, namely the Ontario *Pharmacy Act, 1991* and the *Drug and Pharmacies Regulation Act.*[34] In its material filed in response to this application, the government does not seek to rely on conflict of interest as a basis upon which to support the validity of the regulations.

[73] However, the respondents continue to rely upon the other rationale advanced by the Executive Officer and maintain that the PLP provisions are consistent with maintaining low prices for drugs and with the ban on rebates. In my view, this argument is without merit.

---

[34] *Pharmacy Act, 1991*, S.O. 1991, c.36 and O. Reg. 681/93 (defining professional misconduct for pharmacists); *Drug and Pharmacies Regulation Act*, R.S.O. 1990, c. H.4 and R.R.O. 1990, Reg. 551, s. 46 (dealing with conflicts of interest in the practice of pharmacy).

[74] First of all, any profit earned by a manufacturer in the position of Sanis is not a rebate, and is not like a rebate. The problem with rebates is that they made it impossible for manufacturers supplying pharmacies to lower their prices, and thereby artificially inflated the cost of drugs to the consumer. A manufacturer would sell a generic drug to a pharmacy at a stipulated price and the pharmacy would then sell the drug to the public or to government at prices stipulated by the government. However, manufacturers paid pharmacies what amounted essentially to kick-backs in order to induce them to purchase their brands, with the result that the amount being received by manufacturers was substantially less than the price actually paid by pharmacies. The manufacturers were unable to lower their prices and still be viable, and the "incentive" rebate payments they were making to pharmacies were not passed on to consumers because the consumer price was a mark-up over the purchase price by the pharmacy. Government studies showed that a substantial portion of generic drug costs was reflected in these rebates. The government's solution was to eliminate rebates and to lower the cost of the generic drug. This is clearly within the purpose of the legislation.

[75] Under the new regulations, manufacturers will still purchase from fabricators and will still sell to pharmacies at stipulated prices. Pharmacies will then sell to consumers, at a price wholly controlled by the government. There is no provision banning arms-length manufacturers from operating between the fabricators and the pharmacies and no attempt to ban manufacturers from earning a profit as a result of this business activity, even where the manufacturer is not a fabricator of the generic drug in question. All the PLP provisions accomplish is to prevent pharmacies from having an interest in a company that is a manufacturer if the fabricator is at arm's length.

[76] If Sanis were permitted to operate as proposed by Shoppers, and if Sanis earned a profit from its activities, it is simply not possible to characterize that profit as a rebate. It has no corresponding impact on the price paid by the consumer, nor on the price paid by the pharmacy. Sanis is required to make its products available to other pharmacies at the same price offered to Shoppers. It is in the same position as other manufacturers carrying on the same business. The only difference is found in its corporate structure and the fact that the pharmacy, as an owner of Sanis, will share in any profit earned by Sanis. That is not at all similar to the rebate issue.

[77] Second, the prohibition of PLPs does not lower the price of drugs paid by consumers. In the absence of generic drugs supplied by Sanis, Shoppers Drug Mart will continue to obtain generic drugs from other suppliers and will sell them to the public at the price fixed by the government. Shoppers Drug Mart will lose the potential to benefit from any profits earned by its subsidiary, but this will have no impact on the price of the drugs it sells to consumers.

[78] Third, permitting private label drugs cannot raise the price of generic drugs to consumers. Those prices are fixed by the government. If private label drugs have any impact at all on prices charged to the consumer, it can only be to lower them. A pharmacy that carries its own private label products may be in a position to do that by virtue of the reduced overall costs to the pharmacy after factoring in any profits made in the subsidiary. However, it is never in a position to raise the price of drugs to the consumer; those are fixed by the government.

[79] Fourth, the government's position presupposes that any cost savings obtained by Sanis will not be passed on to the consumers. While that may be true, it is certainly not inevitable. It is merely an assumption made by the government. What is crystal clear, however, is that banning the PLP products cannot possibly save the government or the consumer a cent.

[80] It is apparent from the materials filed, and from the legislation itself, that the government's real concern is that larger pharmacy chains (such as Shoppers Drug Mart and the Katz Group) have found a way to make a profit from the supply and sale of generic drugs at an earlier place in the supply chain than at the point of sale to consumers. They achieve this not by manipulating prices or by artificial kickbacks, but rather through corporate ownership. By owning their own manufacturer, they can keep for themselves the profit that would otherwise be made by arms-length manufacturers. However, these corporations are conducting a business and are in business to make a profit. If through business structure and economies of scale they are able to maximize their overall profit without increasing the price paid by the government or consumers for generic drugs, I do not see how the purposes or objects of the legislation are affected. Indeed, the legislation already provides for similar economies by permitting normal volume discounts and early payment incentives with respect to the prices paid by pharmacies to their suppliers.

[81] In short, there is no concern about the safety or efficacy of the private label products. They will be sold to the public and to the government for precisely the same price as other equivalent generic drugs supplied under different labels by other manufacturers. The government's concern is directed at profits being made by corporations that both own a manufacturer and franchise pharmacies or own pharmacies. Controlling the profitability of such corporations is not a legitimate object or purpose of the ODBA or the DIDFA, provided it has no corresponding cost to the consumer, which it does not.

[82] Accordingly, I find that the PLP regulations do not fall within the purpose and object of the enabling statutes and are therefore *ultra vires*.

G. INTERFERENCE WITH RIGHT TO TRADE

[83] There is a common law presumption that any interference with the right to trade or property rights is invalid unless supported by specific statutory authority. In his text, Professor Mullan states:[35]

> When ruling on the validity of subordinate legislation, the courts frequently invoke common law presumptions as a guide to interpretation. These presumptions require specific rather than general authority to support subordinate legislation affecting certain subject matters or interests, including: ... interference with property rights; ... or interference with the common law right to trade.

---

[35] Mullan, *supra*, note 16, at §514. See also Brown and Evans, *supra* note 17, §15:3240, at p. 15-51.

[84] This principle was applied in *Bomberry*,[36] a case involving a tobacco quota imposed on Indian retailers on a reserve. The Divisional Court held that imposing a quota on a retailer "represents a significant interference with his freedom to buy and sell" and "interferes with his commercial freedom". The Court then noted that, "that kind of power over individual conduct requires very clear statutory authority." Althought there was a broadly worded regulation-making power in the enabling legislation, the Court found this was not sufficient to rebut the presumption against the interference with the right of trade. In the absence of express language authorizing a quota system, the Court found the regulation in question to be invalid.

[85] The PLP provisions are even more intrusive than the regulation struck down by the Divisional Court in *Bomberry*, which was only a quota system, not a complete prohibition. Essentially, the regulations in issue here prohibit a corporation that owns a pharmacy from also owning a generic drug manufacturer, unless the manufacturer is also fabricating its own drugs. Further, this is done in order to restrict profits that can be earned by a corporation in the pharmacy business. This is a significant interference with the property rights and commercial freedom of the corporation, as the regulation prohibits it from engaging in an otherwise legal business activity through its subsidiary. It is also a significant interference with the freedom of the subsidiary company to engage in a trade which is its whole source of business. That is not to say that these kinds of restrictions are beyond the power of the legislature to impose. However, there must be express legislation enabling such control. It cannot be done under the authority of the regulation-making power currently in the enabling statutes.

[86] Therefore, I would also find the PLP provisions to be invalid on this ground.

H. CONCLUSION AND ORDER

[87] The private label drug ban is extraneous to the purposes and objects of the ODBA and the DIDFA. It is also beyond the scope of the regulation-making power in the parent statute and is prohibitory, rather than regulatory. Further, it interferes with the right to trade and commercial freedom, without any specific authority to do so. Any one of these defects is sufficient to render the regulation invalid. In combination, the defects are even more overwhelming.

[88] The Shoppers Drug Mart applicants also argued that the private label prohibitions are invalid because they constitute unauthorized discrimination against private label drug manufacturers. In light of my findings on the other issues raised, it is not necessary to deal with this issue, and I refrain from doing so.

[89] Accordingly, I would grant the relief sought in the form of an order declaring that s. 12.02 of Ontario Regulation 201/96 made under the ODBA and s. 9 of Ontario Regulation 935 made under the DIDFA are *ultra vires* and of no force and effect.

---

[36] *Bomberry supra*, note 23, at pp. 539-541.

[90] If the parties cannot agree on costs, written submissions may be addressed to the Court within 30 days of the release of this decision.

MOLLOY J.

WHALEN J.

SWINTON J.

Released: January 3, 2011

CITATION: Shoppers Drug Mart Inc. v. Ontario, 2011 ONSC 615
DIVISIONAL COURT FILE NO.: 332/10 and 334/10
DATE: 20110203

ONTARIO
SUPERIOR COURT OF JUSTICE
DIVISIONAL COURT

WHALEN, MOLLOY and SWINTON, JJ.

BETWEEN:

Divisional Court File No. 332/10
SHOPPERS DRUG MART INC., SHOPPERS DRUG MART (LONDON) LIMITED and SANIS HEALTH INC.

Applicants

– and –

MINISTER OF HEALTH AND LONG-TERM CARE and LIEUTENANT GOVERNOR IN COUNCIL OF ONTARIO

Respondents

AND BETWEEN:
Divisional Court File No. 334/10

KATZ GROUP CANADA INC., PHARMA PLUS DRUG MARTS LTD., and PHARMX REXALL DRUG STORES LTD.

– and –

MINISTER OF HEALTH AND LONG-TERM CARE and LIEUTENANT GOVERNOR IN COUNCIL OF ONTARIO

Respondents

REASONS FOR JUDGMENT

WHALEN J.
MOLLOY J.
SWINTON J.

Released: February 3, 2011