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CASE LAW UPDATE

Tiffany Tsun *

Shoppers Drug Mart Inc. v. Ontario

2011 ONSC 615 (Divisional Court) (Released February 3, 2011)

Generic Drugs – Regulatory Provisions – *Ultra Vires*

In this case three judges of the Divisional Court ruled invalid two Ontario regulations which purported to prevent the sale of "private label" generic drugs. Private label drugs are made by non-arm's-length companies owned or controlled by pharmacies. The court heard parallel judicial review applications from the Shoppers Drug Mart group of companies and the Katz group of companies (which includes Pharma Plus and Rexall Drug Stores) (together the "Pharmacies"). In the result, the court declared that section 12.02 of Ontario Regulation 201/96 and section 9 of Ontario Regulation 935 were *ultra vires* and of no force and effect.

Health Canada must approve a prescription drug before it can be sold anywhere in the country. Ontario exercises further control via two interconnected legislative schemes: the *Ontario Drug Benefit Act*, R.S.O. 1990, c. O.10 ("ODBA") and the *Drug Interchangeability and Dispensing Fee Act*, R.S.O. 1990, c. P.23 ("DIDFA").

The ODBA governs conditions under which the government will pay pharmacies for prescription drugs provided to eligible persons (such as seniors and persons on social assistance). Under the ODBA, a generic drug not listed on the "formulary" is excluded from reimbursement coverage and excluded from the "public" market. The DIDFA governs the sale of prescription drugs to the general public. Under the DIDFA, a generic drug cannot be sold in the "private" market unless the Ontario Ministry of Health and Long Term Care designates that drug as "interchangeable" with the relevant brand-name drug.

In 2010, the Ontario government introduced amending provisions which effectively prohibited the Pharmacies from selling their own private label generic drugs instead of purchasing those generic drugs from an arm's-length third party. This prohibition would apply even where the law otherwise permitted substitution of generic drugs for brand-name drugs. The policy basis for the regulations was government concern that non-arm's-length pharmacies would dispense their own private label drugs in preference to those of others, and that pharmacy-controlled organizations would retain profits without benefiting consumers.

Justice Molloy for the court provided three reasons to declare the provisions invalid. First, the impugned provisions fall outside the regulation-making authority delegated by the parent statutes. A delegated authority to impose conditions on an activity does not authorize a prohibition of the activity. The regulations' language and their pith and substance were prohibitory.

Second, the provisions do not fall within the purpose of the parent statutes, which is to control prescription drug costs without compromising safety. Instead, the government's evident concern was the profits to be made by large pharmacy chains. Controlling the profitability of such corporations is not a legitimate object or purpose of the parent statutes.

Finally, the provisions constitute an interference with property and commercial rights that is not expressly authorized by the parent statute. There is a common law presumption that any interference with the right to trade or property rights is invalid without specific statutory authority. In this case, there was no express legislation to validate the intrusive interference imposed by the private label drugs provisions.

*Tiffany Tsun is an Associate at WeirFoulds LLP (www.*weirfoulds.com*).