

No Need to Speculate; Injury Required: Ontario Superior Court Dismisses Certification in Proposed Product Liability Class Action

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Introduction

On August 12, 2022, the Ontario Superior Court of Justice dismissed the plaintiffs' motion to certify a proposed class action against manufacturers of valsartan: a blood pressure medication.¹ The plaintiffs alleged that the defendants' products were negligently manufactured because they contained N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) (two molecules allegedly identified as being potentially carcinogenic) and sought to certify the class action on behalf of all persons who had been prescribed the defendants' valsartan products by their physicians.

The action was filed following voluntary recalls by Sandoz and Teva, along with several other pharmaceutical companies, and Health Canada notices announcing that NDMA had been found in the valsartan products.

The plaintiffs alleged that the defendants exposed the putative class members to an increased risk of developing cancer and brought claims in negligence, strict liability, toxic battery, breach of consumer protection laws, breach of the *Civil Code of Quebec*, breach of the *Competition Act*, and unjust enrichment.² In terms of relief, the plaintiffs and putative class members were seeking the costs of medical services related to the recalls, the costs of medical consulting and screening services, refunds for the amounts paid for the drug from 2012 to 2018, the cost of unused pills thrown away after the recall, psychological harm damages and punitive damages.

Notably, the plaintiffs made no claims for compensation for consumers who, after ingesting valsartan, were diagnosed with cancer at present or in the future.

The Certification Decision

In order for a class action to be certified, plaintiffs are required to show "some basis in fact" (a low evidentiary standard) for each of the certification requirements set out in section 5(1) of the *Class*

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Proceedings Act, 1992, other than the purely legal requirement that the pleading discloses a cause of action.

In this case, Justice Perell concluded that the plaintiffs failed to satisfy the cause of action, common issues and preferable procedure requirements as required for certification pursuant to s. 5(1) of the *Class Proceedings Act, 1992*. Most particularly, Justice Perell found that the plaintiffs failed to properly plead or provide any basis in fact for the allegation that the class had suffered actual compensable harm.

Justice Perell held that the plaintiffs' claims contained a "fatal flaw in seeking damages for the harm of an increased risk" as "the current law is that the creation of risk is not harmful conduct." The current law in Canada instead requires actual physical injury to a person or property or psychological harm to a person that has actually materialized.

On the evidence before him, Justice Perell concluded that there was some basis in fact for the proposition that the exposure to NDMA and NDEA "very modestly increases the risk of being diagnosed with cancer"; however, Justice Perell found that the evidence did not show any association between NDMA or NDEA and cancer in humans. In other words, there was no evidence showing some basis in fact for the proposition that NDMA or NDEA actually causes cancer.

With respect to the psychological harm claims, although the Court concluded that there was some basis in fact to the assertion that some putative class members experienced psychological harm, that harm was not compensable since it was no more than the "anxiety occasioned by the risk of future physical or psychological harm." Additionally, expert evidence did not establish that the plaintiffs proved a mental disturbance that rose above the ordinary annoyances, anxieties and fears that come with living in civil society.

Finally, without making a claim for and without establishing some basis in fact for the allegation that NDMA or NDEA causes cancer (i.e., without proof that the product was dangerous to humans), the plaintiffs' claims for pure economic losses for an alleged increased risk of being diagnosed with cancer were not tenable.

Justice Perell also dismissed all other proposed causes of action, which he concluded were doomed to fail.

The Upshot

This case throws a wrench into a spate of class action claims across Canada that have sought to avoid the evidentiary difficulties of proving the causation of cancer and other conditions of uncertain origin by seeking damages for an increased *risk* of harm and medical *monitoring*, rather than suffering actual harm and receiving than treatment for disease. This case confirms that the current state of the law in Canada provides

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remedies for “concrete injuries” but not “abstract or speculative” ones.

As Justice Perell summarized at paragraph 11 of the decision, “in product liability cases, compensation is allowable only for concrete damage caused by the defective or dangerous product, and not for the abstract apprehension that an increased likelihood of cancer can generate.”

¹ *Palmer v. Teva Canada Ltd.*, 2022 ONSC 4690

² A claim for breach of the *Trademarks Act* was abandoned during the hearing of the certification motion.

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