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IN THIS ISSUE

This article discusses a recent decision of the Court of Appeal for Ontario, which affirms dismissal of a motion to certify a proposed class action related to alleged NDMA contamination in Valsartan, a prescription drug. The Court's decision, which is in line with other recent landmark Canadian product liability cases, affirms that Canadian law does not provide remedies for theoretical or speculative risks because actual harm, not just risk of harm, is required for recovery in tort.

Ontario Court of Appeal Affirms the Need to Establish Actual Harm in Negligence Claims

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1. Introduction

Recent landmark product liability decisions in Canada, including the Ontario Superior Court's decision in *Palmer v. Teva Canada Ltd.*, have held that Canadian law does not provide remedies for an increased risk of harm. On appeal from the decision in *Palmer*, the Ontario Court of Appeal has affirmed this line of authority, making clear that actual harm, not just risk thereof, is required for recovery in tort.

2. Background

In *Palmer*, the Ontario Superior Court dismissed a motion to certify a proposed class action related to alleged contamination in "valsartan", a prescription drug for treating high blood pressure.

The plaintiffs' claim alleged, among other things, that the defendants breached their duty of care to the plaintiffs by failing to ensure that the valsartan they produced was free of the contaminants "NDMA" and "NDEA", which they said were carcinogenic. As a result, the plaintiffs claimed damages for an increased risk of harm, psychological harm arising from the recall notice, as well as costs for medical monitoring, medical services, and costs for drugs thrown away.
The motion judge held that the plaintiffs' action failed to make out a claim or establish some basis in fact that NDMA or NDEA causes cancer, and therefore their action was for pure economic losses for an alleged increased risk of being diagnosed with cancer after ingesting NDMA or NDEA. Such a case was not certifiable because it was about compensation for an apprehension of an abstraction (increased risk of diagnosis of cancer) when the normative risk of a class member being diagnosed with cancer in his or her lifetime would have been 50:50, regardless of whether the class member ingested valsartan. The motion judge made clear that the law provides remedies for actual injuries, not future or speculative ones.

On appeal, the Court of Appeal for Ontario affirmed the motion judge's decision (see *Palmer v. Teva Canada Limited*, 2024 ONCA 220). Its key findings and takeaways are discussed below.

3. Key Findings

a. Actual Harm

The overriding hurdle facing the appellants was that no present damage had materialized. On appeal, the appellants argued that their claim pleaded two types of "actual" harm: (1) genotoxic injury (i.e., cellular, or molecular changes to their body caused by ingesting NDMA and NDEA); and (2) psychological injury.

The Court rejected the appellants' assertion that genotoxic injury constituted present actual harm, holding that a physical change with no perceptible effect upon one's health is not compensable in negligence. This claim therefore had the same flaw as the claim for increased risk of cancer – there was no materialized damage.

With respect to the psychological injury claim, the Court accepted the appellants' argument that there could be a cause of action for present psychological harm occasioned by the risk of future physical harm (i.e., a cancer diagnosis). However, the Court stated that the appellants' claim was not viable because the psychological injuries alleged did not rise above ordinary annoyances and were not "serious and prolonged". Further, the Court found that the injury was not foreseeable in a person of ordinary fortitude.

Notably, the Court observed that the recall notices stated that the increased risk of developing cancer was between 0.0086% and 0.0011% in the context of a 50% existing lifetime risk of developing cancer. As such, the Court concluded that the recall would not cause a person of reasonable fortitude to sustain a psychological injury at a level compensable in tort. To the contrary, the Court found that the notices seem intended to assuage concern.

The Court also observed that, in any event, psychological damage claims are often inherently individualized and, as such, do not satisfy the commonality requirement.

b. Pure Economic Loss

The Court also dismissed the appeal from the motion judge's decision not to certify the appellants' negligence claim grounded in pure economic loss, namely, damages for medical services and monitoring, costs thrown away, and refunds. Pure economic loss is only recoverable when the product presents an imminent real and substantial danger, and only for the costs of averting such danger.

Here, the Court found that the plaintiffs' pleading did not establish that valsartan was imminently dangerous. Further, the Court found it plain and obvious on the pleadings that discarding the product was feasible and sufficient to avert any danger. Recovery for economic loss does not extend to other losses such as replacement value for the contaminated product (or refund). Nor is there a path for recovery of medical expenses or medical monitoring without a viable claim in negligence for physical or psychological damages.

c. Consumer Protection Legislation and the Competition Act

Finally, the Court rejected the appellants' claim that the respondents breached the *Consumer Protection Act* by making false, misleading, deceptive, or unconscionable representations about valsartan. The essence of the appellants' case was a negligence claim for a contaminated product, not a deceptive misrepresentation. The statutory remedies under the Act were not available because there was no allegation or material facts to support an allegation that valsartan was unfit for its intended purpose or that the contaminated valsartan was a useless or ineffective drug for the purpose of treating hypertension.

With respect to the appellants' *Competition Act* claim, the Court found that the motion judge did not err in finding that none of the pleaded misrepresentations were capable of sustaining a cause of action under the Act. The Court made clear that the purpose of section 52(1) is to target deceptive marketing practices, not create liability for defective products.

4. Key Takeaways

This decision highlights the importance of requiring actual harm in product liability cases. It confirms that Canadian law does not provide remedies for theoretical or speculative risks as actual harm (compensable damage) must be alleged. The decision also confirms that a claim for psychological injury arising from notice of an increased risk will be struck if it fails to meet the basic threshold of injury needed to garner recovery and the ordinary fortitude test.

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