Ontario Court of Appeal provides guidance on ‘risk of harm’ claims and common issues test

April 23, 2024

On March 27, 2024, the Court of Appeal for Ontario released its decision in *Palmer v. Teva Canada Limited*, 2024 ONCA 220, which upheld a decision of Justice Perell denying certification of a proposed pharmaceutical class action.

In *Palmer*, the Court of Appeal addressed the viability of product liability claims arising from mere exposure to risk, emphasized the limited recovery of pure economic losses in product liability cases, and endorsed the “two-step” test for common issues under the *Class Proceedings Act, 1992*.

Background

In 2012, the supplier of the active ingredient that several pharmaceutical companies used in generic versions of a high blood pressure medication called valsartan changed its manufacturing process. As a result, certain lots of generic valsartan sold in Canada were contaminated with two organic compounds, NDMA and NDEA. These two compounds may be carcinogenic in humans, although are also found in the environment, in drinking water, and in the air.

In 2018, certain lots of valsartan were voluntarily recalled in Canada because of the contamination issue, and Health Canada published several bulletins about these recalls. The overall message from Health Canada was that, although the organic compounds had been identified as potential carcinogens, there was no immediate risk to patients taking these medications and that patients should continue taking their medication unless advised to the contrary by a physician or pharmacist. A study conducted by Health Canada found that the theoretical additional cancer risk, in a worst-case scenario, ranged between one additional cancer case in every 11,600 persons to one additional cancer case in every 93,400 persons.

The proposed class action

Following the voluntary recalls, a proposed class proceeding was commenced against the manufacturers of valsartan that contained the two organic compounds. Significantly, the central thrust of the proceeding was to recover damages for the *potential* increased

risk of being diagnosed with cancer in the future as a result of ingesting contaminated valsartan.

In August 2022, Justice Perell of the Ontario Superior Court of Justice dismissed a certification motion, explaining that this central thrust was a “baffling and fatal feature” of the proposed class action (2022 ONSC 4690).

The Court of Appeal’s decision

The plaintiffs appealed to the Court of Appeal, arguing that Justice Perell committed several errors, including with regard to whether the claim disclosed a cause of action and whether the common issues criterion was satisfied. The Court of Appeal unanimously dismissed the appeal.

1. The viability of the plaintiffs’ claims

The Court of Appeal affirmed that none of the causes of action asserted by the plaintiffs (which included negligence, battery, and breach of the *Consumer Protection Act*) were viable.

In dismissing the negligence claim, the Court of Appeal confirmed that: “Damage (injury) to a plaintiff is an essential element in a claim of negligence” and recognized that the plaintiffs’ claim for increased *risk* of cancer was not sufficient because “damage has not materialized and may never materialize”. The Court of Appeal emphasized the general principle that “there can be no viable cause of action in negligence without actual damage.”

The Court of Appeal also rejected the plaintiffs’ claims based on negligent infliction of psychological injury. The Court concluded that although the claim pleaded a form of injury (i.e. anxiety arising following the publication of the Health Canada bulletins), there was no viable claim because the alleged psychological injuries did not “rise above the anxieties and fears commonly experienced from time to time by people living together in society.” The Court of Appeal added that the Health Canada bulletins were intended to “assuage concern” and “would not cause a person of reasonable fortitude to sustain a psychological injury at the level compensable in tort.”

2. Recovery of pure economic losses

As part of their claim, the plaintiffs sought damages for medical services and monitoring, costs thrown away, and refunds. However, the Court of Appeal concluded that these pure economic losses were not recoverable in tort.

The Court of Appeal relied upon the Supreme Court of Canada’s decision in *Maple Leaf Foods*, which established that, in the context of pure economic loss for dangerous products, plaintiffs can only recover the cost of averting an imminent danger. The Court of Appeal recognized that the plaintiffs were readily able to dispose of the contaminated valsartan and explained: “Where there is no present injury, allowing damages for pure economic loss in the nature of medical monitoring and medical services costs is contrary to the principle that there is no liability for negligence “in the air.””

The Court of Appeal's decision is an important reminder about the limited scope of pure economic losses that can be recovered in the context of product liability class actions.

3. The "two-step" test for common issues

The Court of Appeal also addressed the plaintiffs' argument that Justice Perell erred in refusing to certify common issues regarding general causation.

Justice Perell had concluded that "at this moment in scientific time, while there is some basis in fact for concluding that exposure to NDMA and NDEA increases the risk of being diagnosed with cancer, there is no basis in fact for concluding that NDMA and NDEA cause cancer", and explained that "In fashioning common issues by asserting that there is some basis in fact for an increased risk of cancer while conceding it is premature to conclude that valsartan causes cancer is confounding, confusing, and baffling and makes the general causation issue uncertifiable."

On appeal, the plaintiffs asserted that Justice Perell erred by inappropriately considering the merits of the case and going beyond the "some basis in fact" test for common issues. The Court of Appeal rejected this argument, concluding that the plaintiffs had "failed to show that the finding of the motion judge that there was no basis in fact at this point that NDMA and NDEA cause cancer was palpably wrong." The Court of Appeal explained:

> … While the "some basis in fact" test is a low evidentiary standard, and a court should not resolve conflicting facts and evidence, the court retains a gatekeeping function and certification will be denied if there is an insufficient evidentiary basis for the facts to establish the existence of common issues: *Pro-Sys Consultants*, at para. 103.

The Court of Appeal's analysis, and its explicit reference to the need for an evidentiary basis establishing the "existence" of a common issue, is noteworthy because it constitutes an endorsement of a "two-step" test for certifying common issues. Specifically, in order to certify a proposed common issue, there must be not only a basis in fact showing that the proposed issue can be answered in common across the entire class, but also some basis for the existence of the proposed issue.

The Court of Appeal's support for a two-step approach to certifying a proposed common issue is consistent with a 2020 appellate decision from Ontario's Divisional Court in *Kuiper v. Cooper (Canada) Inc.*, as well as the Federal Court of Appeal's 2023 decision in *Jensen v. Samsung Electronics Co. Ltd.*, which endorsing this "two-step" approach over a "one-step" formulation that focused only on whether a proposed issue could be answered in common across the entire class.

For more information, contact any of the key contacts listed below.

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