Cassels

No Need to Speculate: Ontario Court of Appeal Affirms Denial of Certification in Pharmaceutical Product Liability Class Action Based on Increased Risk of Harm

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Can consumers subject to an increased risk of harm from a product successfully certify a product liability class action even though the harm has not yet, and may never, come to pass? In *Palmer v Teva Canada Limited*, the Ontario Court of Appeal recently confirmed the answer is no.[1]

Background to the Case and Denial of Certification

In the certification decision, covered by our team in a previous article, the Ontario Superior Court of Justice denied certification of the plaintiffs' proposed class action due primarily to the nature of the damages sought by the proposed class members.[2]

The case concerned the alleged contamination of a few lots of the defendants' blood pressure medication, known as valsartan, with trace amounts of two potentially carcinogenic molecules, N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA). Following voluntary recalls by the defendant manufacturers, the plaintiffs sought to certify a class action on behalf of all persons who were prescribed and ingested the defendants' valsartan products.

Importantly, the plaintiffs did *not* allege that they had developed, or would develop, cancer as a result of ingesting the defendants' product. Instead, the plaintiffs sought damages for psychological harm and costs incurred as a result of the increased risk of cancer, including medical services and monitoring, travel costs, reimbursement for wasted time and inconvenience, costs thrown away in disposing of the drug, and refunds – all costs that seemed to be common to the class and easier to certify on a class-wide basis, and that appeared to be costs the class could reasonably incur on the basis of the alleged defect regardless of whether, or why, any of them ultimately developed cancer.

In denying certification, the certification judge found that, while there was some basis in fact for the allegation that exposure to NDMA and NDEA caused or contributed to an increased risk of cancer for the proposed class, there was no basis in fact for concluding that there was a causal relationship between the class members ingesting valsartan and actually being diagnosed with cancer. In other words, on the light standard required for certification of a class action, the plaintiffs had established that the drug could feasibly

have caused a greater *risk* of cancer, but could not establish that those molecules could *cause cancer*. As a result, the court found that there was no viable cause of action due to the lack of any concrete injury suffered by the plaintiffs.

The Decision on Appeal: No Concrete Harm, No Class Action

The Court of Appeal dismissed the plaintiffs' appeal of the lower court's denial of certification for reasons largely aligned with those of the certification judge. In its decision, the Court of Appeal confirmed that the alleged wrongful acts of the defendant manufacturers were non-compensable – not only because physical harm had yet to (and may never) materialize, but also because the harm that *had* potentially materialized (namely, psychological harm from the shock of the recall) was not sufficiently serious to be compensable in tort law.

Tort law, the Court of Appeal reiterated, compensates plaintiffs for actual loss, not the apprehension of potential future loss. The plaintiffs' claims in negligence could not be sustained in the absence of an actual, compensable injury.

On appeal, the plaintiffs focused on what they alleged were two specific errors in the certification judge's conclusions:

1. the certification judge failed to consider *genotoxicity*, or changes to the class members' "internal bodily composition at a cellular or molecular level" caused by NDMA and NDEA as an actual present harm with what they alleged *was* adequate proof of causation; and
2. the certification judge erred in law by concluding that present psychological harm related to the risk of increased cancer (or a future physical injury) was not a viable cause of action.

On the first issue, the class argued that as a result of ingesting valsartan allegedly contaminated with NDMA and NDEA, they suffered genotoxic injury. The Court of Appeal found that the claim for genotoxic injury had the same flaw as the claim for an increased risk of cancer – the damage had not materialized (and it was unclear that it ever would materialize). And even if the evidence had been clear enough on the low certification standard to establish some basis in fact to believe that those substances *did* cause genotoxic injury to the whole class, the plaintiffs' assertion that "molecular changes caused by negligent exposure to toxin is an injury" was not self-evident. Bodies are always undergoing molecular changes, and the plaintiffs had failed to plead why the changes allegedly prompted by these substances were *per se* harmful, apart from their carcinogenic argument that had already failed.

On the second issue, the appellants argued that the certification judge erred by mischaracterizing their claim in psychological harm as one of future harm. The Court of Appeal disagreed, finding that the certification judge had explicitly acknowledged that the claim was for present anxiety. The Court of Appeal did, however,

qualify the certification judge's findings and clarified that there can be a cause of action for present psychological harm occasioned by the risk of future physical harm. In other words, psychological distress caused by a speculative concern of an increased risk is still harm that can be compensable in an appropriate case. That said, the Court of Appeal still found that the plaintiffs had failed to demonstrate that their mental injuries rose "above the anxieties and fears commonly experienced from time to time by people living together in society."[3] The Court referred to Health Canada's advisory that the increased risk of cancer to those who ingested NDMA was between 0.0086% and 0.0011%, which must be considered in light of the 50% existing lifetime risk of any Canadian developing cancer.

The Court also dispensed with a handful of other commonly pleaded claims in product liability class actions that will have some application in a wide array of other pharmaceutical and product liability cases generally:

- **Battery:** There has recently been an uptick in products class actions claiming the tort of battery as a cause of action. These actions claim, in essence, that the class members consented to the product as identified on the package interacting with their bodies, but that they did not consent to interaction with a contaminated or defective product. The manufacturers "touched" them, they assert, with their products in a way to which they did not consent.

The reason for this tortured logic being advanced is because battery – which protects the individual's right to bodily integrity and prevents others from interfering with a plaintiff's body without permission – typically leads to nominal, round-number damages. Since damages for battery are arbitrary round figures, this kind of claim has seemingly presented an ideal shortcut for class counsel seeking to avoid the difficulty of proving damages on a class-wide basis, which is often a fatal vulnerability on a certification motion. If every class member would obtain the exact same arbitrary award, it becomes easier to argue that a class action would meaningfully advance the claims of the whole class.

In finding no certifiable cause of action in battery in *Palmer*, the Court of Appeal confirmed that the claim lacked the necessary element of "direct" physical contact with the plaintiff, finding that the alleged exposure to the contaminated valsartan was insufficient to meet this element of the battery tort, even where the alleged battery is negligent and not intentional. The Court of Appeal also made new law in holding that battery cannot be committed by a failure to act. We expect that these findings will be helpful in limiting the recent proliferation of battery claims in other product liability class actions.

- **Consumer Protection:** Having found that there were no actionable damages to speak of, the Court of Appeal also declined to certify the causes of action based on provincial consumer protection statutes, all of which require some proof of loss.
- **Competition Law:** In a brief assessment of the plaintiffs' competition law claims, the Court of Appeal clarified that: "[t]he object of s. 52(1) [of the *Competition Act*, R.S.C. 1985, c. C-34, which concerns false or misleading representations] is to target deceptive marketing practices, not create liability for defective products."

- **Unjust Enrichment:** The Court of Appeal also dismissed the appeal concerning the plaintiffs' claim for unjust enrichment on the basis of new appellate law in Alberta and British Columbia to the effect that a plaintiff is not "unjustly deprived" for the purposes of product liability claims when they actually receive the product they paid for. If the product is alleged to be defective, the Court of Appeal joined with its parallel courts in holding that negligence, not unjust enrichment, is the appropriate claim.

The Upshot: An Early Exit for Manufacturers Facing Claims of Speculative Harm

The Ontario Court of Appeal's decision in *Palmer* is a very positive one for manufacturers. At its core, *Palmer* underscores a bedrock common law principle for product liability claims: they are fundamentally negligence claims that require proof of injury. *Palmer* helpfully appears to close the door on some of the more recent creative strategies by the class action plaintiff bar to establish damages on a class-wide basis without needing to prove individual harm. The Court of Appeal's decision also supports the conclusions drawn in our previous case comment; an increased risk is not tantamount to injury or harm and the court may look to whether there is an actual perceptible effect upon one's health in determining whether it is compensable in negligence.

The decision does clarify that psychological distress caused by even a speculative concern of an increased risk is still harm, and may be compensable in appropriate cases. To qualify, the Court maintained that the psychological injury would have to be "serious and prolonged" and rise above "ordinary annoyances, anxieties and fears," which in this instance, was not the case. While this is likely a subjective, case-by-case question, which perhaps may not be well-suited to adjudication on a class-wide basis, it is interesting to note that the Ontario Superior Court recently allowed a claim to proceed in respect of mental injury and shock allegedly suffered by a bystander who observed a fatal motor vehicle accident, a decision which our Product Liability Team has also covered. When taken together, these two decisions begin to provide some insight into the level of psychological injury necessary for a successful claim.

All told, *Palmer* provides a helpful precedent for manufacturers in all industries facing proposed class actions based on a speculative risk of increased harm from their products. While class certification has long been recognized as a low bar that does not involve close scrutiny of the merits, *Palmer* suggests that claims such as this, where no serious present harm has materialized, will still fail to clear that low bar and will be subject to early dismissal at the certification stage.

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[1] *Palmer v Teva Canada Limited*, 2024 ONCA 220, <https://canlii.ca/t/k3q9w> [*Palmer*].

[2] *Palmer v Teva Canada Limited,* 2022 ONSC 4690, <https://canlii.ca/t/jrfdz>.

[3] *Palmer*, at para. 66.