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IN THIS ISSUE

The article discusses a recent decision of the Ontario Superior Court, which dismissed a motion to certify a proposed class action related to alleged NDMA contamination in valsartan, a prescription drug. It illustrates how plaintiffs proceeding to certification without evidence of causation of harm will face an uphill battle to have their proposed class actions certified given the centrality of evidence of causation of harm in product liability claims.

'Snail in the Bottle' Case Revisited – Certification of Valsartin/NDMA Class Action Denied

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A recent decision of the Ontario Superior Court dismissed a motion to certify a proposed class action related to alleged NDMA (N-Nitrosodimethylamine) contamination in "valsartan", a prescription drug for treating high blood pressure.[1]
The certification motion raised a "what if" legal question invoking the iconic 'snail in the bottle' case of *Donoghue v. Stevenson*:

> What if the 29-year-old May Donoghue went to her doctor to be examined, would the manufacturer of the ginger-beer be liable to pay the doctor's bill if the diagnosis was "May, as far as I know, you're quite fine after that distressing incident; here's my bill"?

Over eight decades later, Justice Perell of the Ontario Superior Court answered this question in the negative, holding that Canadian law provides remedies only for concrete injuries.

(1) The Claim

Justice Perell described the basis for the plaintiff's claim in the following terms: n 2018the manufacturers of valsartan recalled some lots of their pharmaceutical product in Canada and other countries because the lots were contaminated with NDMA and NDEA (N-Nitrosodiethylamine). The source of the contamination was a Chinese manufacturer and a subcontractor supplier of valsartan.

The plaintiffs and class members, persons who were prescribed valsartan by their physicians, sued the defendant pharmaceutical companies for (1) negligence/product liability; (2) strict liability; (3) toxic battery; (4) breach of consumer protection laws; (5) breach of the *Civil Code of Quebec*; (6) breach of the *Competition Act*; and (7) unjust enrichment.
By way of remedies, the plaintiffs and class members sought (1) the costs of medical services related to the recall; (2) the costs of medical consulting and screening services; (3) refunds for the amounts paid for the drug from 2012 to 2018; (4) the costs of the unused pills thrown away after the recall; (5) psychological harm damages; and (6) punitive damages.

The plaintiffs made no claim for compensation for consumers who, after ingesting valsartan, were diagnosed with cancer at present or in the future. They asserted that this case is about compensation for *increasing the risk* of a cancer diagnosis and not about compensation for suffering cancer now or in the future as a result of ingesting valsartan.

(2) The Motion for Certification

In Canada, class action legislation does not grant an automatic right to proceed with a class action. A party must first obtain court approval by having its proposed class action "certified". At issue in this certification

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

motion was whether the proposed class action meets the certification criteria in Ontario, namely:

(1) the pleadings disclose a cause of action;
(2) there is an identifiable class of two or more persons that would be represented by the representative plaintiff;
(3) the claims of the class members raise common issues;
(4) a class proceeding would be the preferable procedure for the resolution of the common issues; and
(5) there is an adequate representative plaintiff.

The plaintiff must show "some basis in fact" for each of the certification requirements other than the requirement that the pleading discloses a cause of action to which the "plain and obvious" test applies.

(3) Outcome

Justice Perell refused to certify the proposed class action on various grounds.

(4) The Central and Fatal Finding

Fatal to the plaintiffs' proposed class action was that, without making a claim for and without establishing some basis in fact that NDMA or NDEA causes cancer, the plaintiffs' action is for pure economic losses for an alleged increased risk of being diagnosed with cancer after ingesting NDMA or NDEA. Such a case is not certifiable because it is 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 is 50:50, regardless of whether the class member ingested valsartan. The law provides remedies for concrete injuries not abstract or speculative ones.

Justice Perell nonetheless addressed the issue of causation, holding that "if the statistics from the studies and experiments indicate that exposure to NDMA or NDEA increases the experience of cancer, that is a necessary but not a sufficient basis for concluding that NDMA and NDEA are carcinogens in humans".

Justice Perell also held 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". Further, "the measure of the increased risk to humans from exposure to NDMA and NDEA is very small having regard to the already existing very high risk of human beings experiencing cancer of a lifetime". He also noted that no scientific or regulatory body has definitively classified NDMA or NDEA as a carcinogen for human beings.

Therefore, Justice Perell held that there is no basis in fact to conclude that valsartan causes cancer.

However, Justice Perell accepted that "as a general matter, there is some basis in fact for the proposition that the exposure to NDMA and NDEA in the Defendants' contaminated valsartan very modestly increases the risk of being diagnosed with cancer". But he held that that is insufficient to sustain a cause of action against the defendants.

(5) <u>Key Takeaways from Justice Perell's Reasons</u>

(a) Cause of Action Criterion

Negligence/Product Liability

In product liability cases involving allegations of psychological harm, the plaintiff must show more than mere creation of risk. There is no right to be free from the *prospect* of damage; rather, there is only a right not to *suffer* damage that results from exposure to unreasonable risk. And, in any event, where the evidence reveals that a significant portion of the class will not be able to show they have a compensable claim for psychological injury, the common issues and preferable procedure criteria would be at best "only tenuously satisfied, if they are satisfied at all".

Further, a products liability claim for pure economic losses for shoddy and not imminently dangerous goods will not satisfy the cause of action criterion. It is a predicate for recovery for pure economic loss that the goods present an imminent real and substantial danger to health and safety. Latent but presently unproven causation of harm is the opposite of imminent danger. Even if it could be shown that the defendants had a duty of care and breached the standard of care, proof of causation of harm is required. In short, no harm, no liability.

Strict Liability

While there is a tort of strict liability associated with nuisance and damage to real property, Canadian law has not extended the principles of strict liability to product liability claims. Strict liability also requires proof of damage.

Toxic Battery

In Canada, a person will be liable for battery if they intentionally inflict unconsented physical contact on the plaintiff whether or not damage is caused.

A battery cause of action is not certifiable where the pleaded material facts are allegations of negligence. Nor is it certifiable where the type of battery alleged is in respect of medical treatment, the treatment was consensually prescribed, and there is no evidence that the ingestion of the drug failed to treat the relevant medical condition. Finally, no purpose would be served by having a common issues trial about battery where class members would have occasioned no harm from the battery.

Breach of Consumer Protection Laws

Whether a plaintiff's breach of consumer protection statutes claim discloses a certifiable cause of action should be considered in light of the remedies the plaintiff actually seek. For instance, in this case there was no basis in fact or in law that damages are a remedy for the breach of the consumer protection statutes because there are no compensable damages for an increase of a risk of a personal injury and the damages for refunds and for the expense of pills thrown away are *de minimis* and the claims do not satisfy the preferable procedure criterion.

As for the claim for refunds and the cost of unused pills, valsartan is not alleged to be unfit for its intended purpose of treating hypertension and there is no suggestion that the contaminated valsartan was a useless or ineffective drug for the purpose to treating hypertension. This circumstance makes the claim for refunds and the wasted pills *de minimis* and the preferable procedure criterion unsatisfied.

In addition, the consumer protection statutes aim at prohibiting and punishing *intentional* acts of misrepresentation and unfair business practices.

Breach of the Competition Act

A failure to disclose a non-dangerous defect in a product is not a representation for the purposes of section 52 of Canada's *Competition Act*, which deals with false or misleading representations.

Further, to establish a breach of section 52 (1) and to obtain damages under section 36 (1), a plaintiff must prove actual loss or damage caused by a materially false or misleading representation. In this case, for instance, the claim for psychological harm is uncertifiable and there is no compensation for the harm of an increased risk and, thus, there can be no causal connection to damages when there are no damages.

Unjust Enrichment

In Canada, the elements of unjust enrichment are (1) the defendant has been enriched; (2) the plaintiff has suffered a deprivation that corresponds to the defendant's enrichment; and (3) the absence of any juristic reason justifying the defendant's retention of that transfer of value.

None of these elements was met in this case. First, there has been no transfer of money, goods, or valuable services from the class members to the defendants. The class members dealt directly with the pharmacies or hospital dispensaries that dispensed valsartan, which is a prescription drug. There is not even an indirect transfer of wealth in this case because up until the recall, the class members received value in exchange for what they paid or what was paid for them for the drugs, which no one suggests did not serve their indicated purpose of treating hypertension.

Second, the deprivation that the class members suffered was non-monetary; it was a deprivation in the quality of the valsartan that had been purchased.

Finally, the contract of sale between the defendants and the retailer of the pharmaceuticals is a juristic reason for the transfer of wealth.

(b) Identifiable Class Criterion

The definition of an identifiable class serves three purposes under Canadian law: (1) it identifies the persons who have a potential claim against the defendant; (2) it defines the parameters of the lawsuit so as to identify those persons bound by the result of the action; and (3) it describes who is entitled to notice.

In this case, the plaintiffs originally proposed the following class definition: "All persons in Canada who purchased or ingested one or more of the valsartan products identified by Health Canada in the Recall List dated July 9, 2018 or in any future such recall lists". They later proposed a broader class:

All persons in Canada who purchased or ingested one or more of the valsartan products manufactured and/or distributed by the defendants identified by the DINs listed on the Health Canada Recall List dated November 28, 2018 (the "Class Members") between January 1, 2012 and December 1, 2018 (the "Class Period").

As a technical matter, the class definition criterion was satisfied. However, if there are no certifiable causes of action, the satisfaction of the class definition criterion is a moot point.

(c) Common Issues Criterion

The plaintiffs failed to satisfy the common issues criterion because there are no certifiable causes of action in part because: (a) apart from the matter of damages for emotional distress, there is no basis in fact that the putative class members suffered any compensable harm; and (b) insofar as genuine emotional distress was experienced, it was connected to fear of an increased risk of potential harm, and Canadian law is against compensation for increased potentiality. Thus, there are no causes of action upon which to construct common issues.

While not necessary given the previous finding, Justice Perell nonetheless addressed additional problems with some of the proposed common issues : the general causation, and aggregate and punitive damages issues.

General Causation

In this case, the proposed general causation questions were about whether the contaminated valsartan can increase the risk of cancer, but this is conflated and confused with a general causation question of whether the valsartan can cause harm to human cells all the while not asking whether

or not the harm caused to the cells by the valsartan caused or contributed to a diagnosis of cancer, a more normative general causation issue.

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 and confusing, making the general causation issue uncertifiable.

Aggregate Damages

Where the only remaining issue is the determination of damages, the court may, under certain conditions, make an aggregate award of damages for the benefit of the entire class.

Pursuant to s. 24 (1)(b) of Ontario's *Class Proceedings Act,* for there be a determination of aggregate damages, no question of fact or law other those relating to the assessment of the defendant's monetary liability must remain to be determined in order to establish the defendant's liability.

With the exception of battery, all of plaintiffs' causes of action require the proof of damages, which would entail individual issues trials and thus, these causes of action were not amenable to an aggregate assessment of damages.

The proposed common issue on aggregate damages arising from the battery claim was also rejected, but on different grounds. The battery cause of action is not certifiable and even if it was, a question on aggregate damages on that claim would not have been certifiable. Most class members would not be aware that a metabolic conversion, which could but not necessarily would produce various adverse biological effects, had even occurred when they ingested valsartan, which they were advised to continue to do until advised not to do so by their physician. This sort of alleged trespass to the person is idiosyncratic and not susceptible to a rational assessment of a minimum base level award and therefore not amenable to an aggregate assessment.

Punitive Damages

While the legal justification and the quantification of punitive damages might have to await the outcome of individual issues trials, the question of whether the defendant's conduct warranted punitive damages could be certified as a common issue.

If the case had otherwise been certifiable, Justice Perell would have held that there was no basis on which to certify the punitive damages issue on the filed materials as something other than pleadings are needed to establish a basis in fact for a common issue on punitive damages. However, he would also have left it open to the plaintiffs to revisit the issue later in the action on additional materials.

(d) Preferrable Procedure Criterion

In this case, while there were many complainants, the complaints were largely idiosyncratic and the damages claims – which do not include the genuinely serious claim of a valsartan ingestion causing cancer – were either non-compensable or *de minimis.*

No serious access to justice considerations were present in this case given the litigation design and limitations on the available compensation. Regarding behavior management, pharmaceutical companies are already heavily regulated, and a class action that will yield little to no compensation for most of the class ends up being little more than a licensing fee for bad behavior. As for judicial economy, Justice Perell described the proposed class action as "a howitzer firing BBs and not mortar shots, which is an inefficiency metaphor for a class action with both inefficient overkill and inefficient underkill".

(e) Representative Plaintiff Criterion

As for the representative plaintiff criterion, the Plaintiffs would have satisfied the representative plaintiff criterion, but the point is moot. It is axiomatic that if the cause of action and or the common issues criterion are not satisfied, the other certification criteria are not satisfied.

(6) Conclusion

This decision highlights the importance of evidence of causation of harm in product liability cases It confirms that Canadian law does not provide remedies for theoretical or speculative risks as there is no right to be free from the prospect of damage. It also confirms that plaintiffs proceeding to certification without evidence of causation of harm will face an uphill battle to have their proposed class actions certified given the centrality of causation of harm in a product liability claim.

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