

## Lowering the Bar? Court of Appeal Rules that Plaintiffs Need Not Identify a Specific Defect in Negligent Design and Manufacture Claims

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**November 9, 2023**

In *Fernandez Leon v Bayer Inc.*, [2023 ONCA 629](#), a recent decision of the Ontario Court of Appeal, the Court overturned a lower court's decision to strike a product liability claim against a medical device manufacturer without leave to amend for failing to plead any particulars of a specific design or manufacturing defect in the medical device at issue.

### Background to the Case

The plaintiff commenced a claim against medical device manufacturer, Bayer Inc., related to injuries suffered by Ms. Fernandez Leon which were alleged to have been caused by an implanted contraceptive device manufactured by Bayer.

The plaintiff's original Statement of Claim pleaded detailed allegations regarding the plaintiff's alleged injuries, but only general allegations of negligent design and manufacture, including that Bayer "knowingly designed, manufactured, distributed, marketed and sold a product that they knew, or ought to have known was defective," without specifying what the alleged defects in the device actually were.

In our civil litigation system, plaintiffs are required to set out all material facts related to their claim in a statement of claim, which allows the defendant to know the case they have to meet. If sufficient material facts are not pleaded, a defendant may bring a motion to strike the claim pursuant to rule 21.01(1)(b) of the *Rules of Civil Procedure* on the basis that the statement of claim fails to disclose a viable cause of action.

Bayer brought such a motion in this case, asserting that the plaintiff's Statement of Claim was defective and did not disclose a cause of action due to the failure to identify a specific alleged defect in the device that caused the plaintiff's injuries. The motion judge at the lower court level agreed and struck the claim without leave to amend. This decision was appealed by the plaintiff.

### The Appeal

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On appeal, the plaintiffs produced a draft Amended Statement of Claim which included new language alleging that the plaintiff's injuries were caused by an alleged defect in the device. Bayer argued the amendments remained deficient because the specific design and manufacturing defects were still not identified in the amended version of the pleading.

The Court of Appeal disagreed and held that the proposed amendments were sufficient to plead the essential elements of a claim for negligent design and manufacture, and that, importantly, the specific defect alleged to have caused the plaintiff's injury does not always need to be pleaded for a claim to disclose a cause of action and avoid being struck.

In particular, the Court of Appeal stated:

We do not agree with Bayer that in every case where a plaintiff alleges negligence in the design and manufacture of a product, the statement of claim must be struck unless it identifies the specific defect in the product that caused the injury. **The particulars of a specific defect are not in our view elements of the tort that are always required to be pleaded before the claim discloses a cause of action. To identify a specific manufacturing or design defect in every case would place too onerous a burden on a plaintiff at the stage of initiating a proceeding in a product liability action.** In this case, involving a medical device that is alleged to have caused injury after it was implanted for its intended use, the appellants meet the requirement to plead a cause of action in negligence, even if they cannot at this time identify a specific defect in the product's manufacture or design. [*Emphasis added*]<sup>1</sup>

The Court contrasted this case from previous cases decided in the context of class actions certification motions, where the plaintiff is required to meet a slightly higher "some basis in fact" threshold of establishing an alleged product defect.

## Key Takeaways

By clarifying that specific identification of an alleged defect is *not* an essential element for a pleading in a product liability claim, this case arguably lowers the threshold for plaintiffs to commence claims and removes a potential tool for manufacturers to seek an early dismissal of the claim by way of a motion to strike a defective claim.

That said, a plaintiff will ultimately need to identify and provide evidence of a defect in order to prove their claim at trial. However, given the reality that most claims are settled before reaching a determination on the merits, this permissive approach to pleadings in product liability cases may result in a higher risk of exposure to frivolous claims as plaintiffs without specific evidence of a defect pursue generically pleaded claims hoping to uncover evidence through the litigation process. In such circumstances, manufacturers and their counsel may be required to take a more aggressive approach to seeking early resolution on the merits.

<sup>1</sup> *Fernandez Leon v Bayer Inc.*, 2023 ONCA 629, <<https://canlii.ca/t/k08tz>>, at para. 12.

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