COURT OF APPEAL FOR ONTARIO

CITATION: Fernandez Leon v. Bayer Inc., 2023 ONCA 629
DATE: 20230922
DOCKET: COA-23-CV-0062

van Rensburg, Nordheimer and George JJ.A.

BETWEEN

Arianna Fernandez Leon and Bolelsaw Brzozowski

Plaintiffs
(Appellants)

and

Dr. George A. Vilos and Bayer Inc.

Defendants
(Respondent)

Johanna Drennan, for the appellants

Grant Worden and Alicja Puchta, for the respondent Bayer Inc.

Heard: August 30, 2023

On appeal from the judgment of Justice Alissa K. Mitchell of the Superior Court of Justice, dated October 17, 2022, with reasons reported at 2022 ONSC 5837.

REASONS FOR DECISION

[1] This appeal concerns a motion in proceedings about an implanted medical device called Essure, a permanent form of female contraception, that is alleged to have caused injury to the appellant, Arianna Fernandez Leon. The action was commenced against the physician who implanted the device in Ms. Fernandez

Leon, and the respondent Bayer Inc. (“Bayer”), the alleged manufacturer of the device. The action was discontinued against the physician.

[2] The appellants appealed the order of the motion judge striking the statement of claim in its entirety without leave to amend. They also sought leave to appeal the costs order of $12,500 in favour of Bayer. At the hearing of the appeal, we set aside the order of the motion judge and granted leave to the appellants to amend the statement of claim, with reasons to follow. These are our reasons.

[3] Bayer’s motion was brought under r. 21.01(1)(b) of the *Rules of Civil Procedure*, R.R.O. 1990, Reg. 194, asserting that the statement of claim did not disclose a cause of action. The motion judge agreed, concluding that there were substantial foundational deficiencies in the appellants’ claim that could not be cured by simply amending the pleading.

[4] Irrespective of the deficiencies that she identified in the appellants’ pleading, the motion judge erred in refusing to grant leave to amend the statement of claim. She did not advert to or apply the test for amendment of pleadings articulated by this court. Instead, the motion judge concluded that there was “no benefit in permitting the [appellants] to try and find some tenable basis in fact for a claim against Bayer when none [had] been found by them to date”.

[5] Leave to amend a statement of claim should be denied only in the clearest of cases, when it is plain and obvious there is no tenable cause of action, the

proposed pleading is scandalous, frivolous or vexatious, or there is non-compensable prejudice to the defendants: see *McHale v. Lewis*, 2018 ONCA 1048, at paras. 6 and 22; *Klassen v. Beausoleil*, 2019 ONCA 407, 34 C.P.C. (8th) 180, at para. 25. This test applies even where it is determined that the statement of claim, as pleaded, should be struck: see *Burns v. RBC Life Insurance Company*, 2020 ONCA 347, 151 O.R. (3d) 209; *Tran v. University of Western Ontario*, 2015 ONCA 295. The fact that allegations are bald and lack supporting material facts is not itself a reason for refusing leave to amend: *Miguna v. Ontario (Attorney General)* (2005), 205 O.A.C. 257, at para. 22.

[6] At the hearing of the appeal the appellants produced a draft amended statement of claim, that, although referred to as an attachment to the appellants' factum, had not in fact been attached or otherwise included in their materials. After the panel reviewed the draft amended pleading, we invited counsel for Bayer to address whether, having considered the proposed amended pleading, leave should be granted to the appellants to amend the statement of claim.

[7] Counsel for Bayer's position was that, although Bayer, quite fairly, would not oppose providing the appellants with an opportunity to amend their pleading, the proposed amended statement of claim that was produced at the hearing of the appeal was still deficient as it did not disclose a cause of action for negligent design and negligent manufacture because the specific design and manufacturing defects

were not identified. It was acknowledged that the proposed amended statement of claim adequately pleads breach of a duty to warn.

[8] The test for striking pleadings for not disclosing a reasonable cause of action is stringent, and the moving party must satisfy a very high threshold in order to succeed. This may occur where the allegations do not fall within a cause of action known to law, or because the statement of claim fails to plead all the essential elements of a recognized cause of action: *Dawson v. Rexcraft Storage & Warehouse Inc.* (1998), 164 D.L.R. (4th) 257 (Ont. C.A.), at para. 10. Unless it is "plain and obvious" that there is no chance of success, a claim, even a novel one, ought to be allowed to proceed. The pleading must be read generously, erring on the side of permitting an arguable claim to proceed to trial: see *Rausch v. Pickering (City)*, 2013 ONCA 740, 369 D.L.R. (4th) 691, at para. 34.

[9] The original statement of claim recites in some detail Ms. Fernandez Leon's medical issues that are alleged to have been caused by the implantation of the Essure device in April 2013. It pleads that the Essure device perforated Ms. Fernandez Leon's uterus. The statement of claim makes 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".

[10] The proposed amended pleading pleads specific facts at para. 36 respecting the connection between Ms. Fernandez Leon's injuries, including perforations of her fallopian tube, uterus and bowel, and her various surgical procedures and complications. Paragraph 36 alleges that the complications were a direct result of a defective product, and that on December 31, 2018 Bayer stopped selling and distributing the device. The proposed new paragraph 42 expands to some extent on the allegations of negligence contained in paragraph 41.

[11] In our view the proposed amendments plead the essential elements of the claims for negligent design and manufacture. The proposed amendments plead the material facts that are required to support the pleaded causes of action. That is, they meet the low threshold for pleading a cause of action.

[12] 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.

[13] Bayer's reliance on two decisions of the Superior Court, *Kuiper v. Cook (Canada) Inc.*, 2018 ONSC 6487, rev'd in part on other grounds, 2020 ONSC 128, 149 O.R. (3d) 521 (Div. Ct.) and *Martin v. Astrazeneca Pharmaceuticals Plc*, 2012 ONSC 2744, is misplaced. Both decisions involved certification motions in proposed class proceedings, where the test for certification includes the identification of proposed common issues and requires the proposed representative plaintiff to meet the evidentiary threshold of showing "some basis in fact" to show a defect in the product or products at issue that is common across the proposed class. In *Vester v. Boston Scientific Ltd.*, 2015 ONSC 7950, by contrast, the proposed representative plaintiff was found to have pleaded a cause of action in negligent design notwithstanding a failure to identify a specific design defect, but her failure to identify a common defect across the various products at issue was fatal to the certification of the action as a class proceeding: at paras. 100-103, 116-126.

[14] We therefore allowed the appeal and granted the appellants leave to amend the statement of claim. The statement of claim shall be amended within 30 days, with the time for delivery of a statement of defence extended accordingly. While we have determined that the proposed amendments are sufficient to disclose a cause of action in negligence in the design and manufacture of the Essure device,

and Bayer has acknowledged that they are sufficient to disclose a cause of action for duty to warn, nothing in these reasons should be taken to require the appellants to limit their amendments to those set out in the proposed amended pleading or to prevent Bayer, once the statement of claim has been amended, from seeking further particulars before it delivers its statement of defence.

[15] The appellants have obtained an indulgence permitting them to amend a statement of claim that was initially deficient. While it is appropriate to set aside the costs in the court below, as the motion judge ought to have granted leave to amend, we order no costs in the court below or on appeal.

"K. van Rensburg J.A."
"I.V.B. Nordheimer J.A."
"J. George J.A."