Canadian Claims for Cancer Risk Rejected in Valsartan and Ranitidine Litigation: A Welcome Development for Manufacturers Doing Business in Canada

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Two Canadian courts have recently rejected claims for genotoxic injury, psychological harm, medical monitoring, and other losses allegedly caused by exposure to medications containing nitrosamine impurities. The decisions in *Dussiaume v. Sandoz Canada Inc.*[1] and *Palmer v. Teva Canada Limited*[2] are a welcome development for manufacturers of pharmaceutical and other products doing business in Canada, where class certification standards are lower than the United States, and certified product liability and toxic tort class actions are relatively common. They send a clear signal that claims based on weak science concerning the risk of future disease that may never materialize will not be certified and will be vulnerable to early dismissal.

I. Canadian Class Action Procedure

Unlike in the United States, product liability and mass tort

[1] [2023] BCSC 795 (Can. B.C.) (hereinafter, "*Dussiaume*").

[2] [2024] ONCA 220 (Can. Ont. C.A.) (hereinafter, "*Palmer ONCA*"), aff'd [2022] ONSC 4690 (Can. Ont.) (hereinafter "*Palmer ONSC*").

claims in Canada are typically litigated through class actions.[3] This is because the standards for class certification in Canadian provinces, especially Quebec, are lower than the standards in the Federal Rules of Civil Procedure[4] and most United States state rules. The allegations in the plaintiff's claim (i.e. complaint) are taken as true, and the standard for the remaining certification criteria (identifiable class, common issues, preferability, and a suitable class representative)[5] is "some basis in fact".[6] The "some basis in fact" standard is frequently characterized—rightly or wrongly—as a low bar.[7] Class certification is said to be a "meaningful screening device", but is decidedly not a determination of the merits, and Canadian certification judges are prohibited from resolving conflicting facts and evidence or engaging in finely calibrated assessments of evidentiary weight.[8] Canadian courts have repeatedly held that judges should not resolve a "battle of the experts" at certification.[9]

There is no direct Canadian analogue to the *Daubert* motion in the United States,[10] although the gatekeeping principles of *Daubert* have been embraced by the Supreme Court of Canada in relation to "novel science".[11] Furthermore, like most civil trials in Canada, common issues trials—which themselves are exceedingly rare—are typically tried without a jury.[12] Canadian courts therefore lack typically the institutional

[3] However, recent amendments to the class proceedings legislation in Ontario may make individual claims and inventory litigation more prevalent. Ontario's class action legislation has been amended to include a requirement for superiority and predominance. *Class Proceedings Act, 1992*, S.O. 1992, c. 6, s. 5(1.1). *See* Deborah Templer, Byron Shaw, and Daniel Moholia, *Inventory Litigation of Mass Torts in Canada: An Uncertain Future*, McCarthy Tetrault, (Jan. 26, 2023) available at https://www.mccarthy.ca/en/insights/articles/inventory-litigation-mass-torts-canada-uncertain-future.

[4] Fed. R. Civ. P. 23.

[5] *See e.g*. Class Proceedings Act, 1992, S.O. 1992, c 6, s. 5.

[6] Hollick v. Toronto (City), [2001] 3 S.C.R. 158, para. 25 (Can.); Pro-Sys Consultants Ltd. v. Microsoft Corporation, [2013] 3 S.C.R. 477, paras. 99-100 (Can.) (hereinafter "*Microsoft*").

[7] AIC Limited v. Fischer, [2013] 3 S.C.R. 949, para. 39 (Can.); Sun-Rype Products Ltd v. Archer Daniels Midland Company, [2013] 3 S.C.R. 545, paras. 57 and 61 (Can.).

[8] *Microsoft*, *supra* note 6, at paras. 102-103.

[9] *Microsoft*, *supra* note 6, at paras. 117 and 126; *see also* Ewert v. Nippon Yusen Kabushiki Kaisha, [2019] BCCA 187, para. 7 (Can. B.C. C.A.); Mancinelli v. Royal Bank of Canada, [2020] ONSC 1646, para. 95 (Can. Ont.).

[10] *See, for example, in re* Zantac (Ranitidine) Products Liability Litigation, 546 F.Supp.3d 1152 (S.D. Fla. 2021);

[11] R. v. J.-L.J., [2000] 2 S.C.R. 600, para. 33 (Can.); R. v. Trochym, [2007] 1 S.C.R. 239, para. 36 (Can.); Andersen v. St. Jude Medical, Inc., [2012] ONSC 3660, para. 44 (Can. Ont.).

[12] *See, for example,* Brousseau c. Laboratoires Abbott ltée, [2016] QCCS 5083 (Can. Que.), aff'd [2019] QCCA 801, leave to appeal to S.C.C. refused, [2020] CanLII 26452; Anderson v. St. Jude Medical, Inc.,

concern articulated in *Daubert* of ensuring expert witness testimony is sufficiently reliable and relevant to present to a jury.[13]

Summary judgment motions are an option for defendants in class actions in common law provinces.[14] However, the standard summary judgment places is relatively high; the moving party must show that there is no genuine issue "for"[15] or "requiring" a trial, depending on the province.[16] Defense motions for summary judgment can also create risk for defendants on certification. Plaintiffs may obtain summary judgment in their favor (in some provinces, the plaintiff does not even need to bring a cross-motion for summary judgment to obtain judgment in their favor).[17] Furthermore, a defense summary judgment motion can risk undermining procedural defenses that the action lacks common issues or is not the preferable procedure for resolving the litigation. For instance, defense arguments that there is no genuine triable issue for want of general causation may be met with a plaintiff's response that general causation is a common issue that will meaningfully advance the litigation.

The combined result of these procedural differences is that, unlike in the United States, product liability and mass tort cases often proceed to class certification and many (though certainly not all)[18]

[2012] ONSC 3660 (Can. Ont.). *But see* Bartram v. GlaxoSmithKline Inc., [2016] BCSC 1409 (Can. B.C.) (declining to strike jury notice in product liability class action concerning medication allegedly causing birth defects).

[13] Daubert v. Merrell Dow Pharmaceuticals Inc., 509 U.S. 579, 595-597 (1993). Many Canadian courts have commented that the gatekeeping role for expert evidence is heightened for cases involving a jury, which are not the norm in most Canadian civil trials. *See, for example,* Bruff-Murphy v. Gunawardena, [2017] ONCA 502, para. 2 (Can. Ont.); Brake-Patten v. Gallant, [2012] NL.CA 23, para. 63 (Can. NL).

[14] *See* Wise v. Abbott Laboratories, Limited, [2016] ONSC 7275 (Can. Ont.); *Dussiaume*, *supra* note 1.

[15] *See, for example*, B.C. Supreme Court Civil Rules, B.C. Reg. 168/2009, R. 9-6.

[16] *See, for example*, Ontario Rules of Civil Procedure, R.R.O. 1990, Reg. 195, R. 20.04(2).

[17] *See e.g.* Kassburg v. Sun Life Assurance Co. of Canada, [2014] ONCA 922, paras. 50-52 (Can. Ont.); Landrie v. Congregation of the Most Holy Redeemer, [2014] ONSC 4008, para. 51 (Can. Ont.).

[18] Examples of product liability claims that have not been certified include Charlton v. Abbott Laboratories, Ltd., [2015] BCCA 26 (Can. B.C.); Martin v. Astrazeneca Pharmaceuticals PLC, [2012] ONSC 2744 (Can. Ont.), aff'd [2013] ONSC 1169; Price v. H. Lundbeck A/S, [2018] ONSC 4333 (Can. Ont.); Singer v. Schering-Plough Canada Inc.), [2010] ONSC 42 (Can. Ont.); Wuttunee v. Merck Frosst Canada Ltd., [2009] SKCA 43 (Can. Sask.), leave to appeal to denied, 32905; Batten v. Boehringer Ingleheim (Canada) Ltd., [2017] ONSC 53 (Can. Ont.), aff'd [2017] ONSC 6098; Ernewein v. General Motors of Canada, [2005] BCCA 540 (Can. B.C.); Koubi v. Mazda, [2012] BCCA 310 (Can. B.C.), leave to S.C.C. denied, 35017 (Jan. 7, 2013); Arora v. Whirlpool Canada LP, [2012] ONSC 4642 (Can. Ont.), aff'd [2013] ONCA 657, leave to appeal to S.C.C. denied,

are certified. Some Canadian courts have suggested that product liability cases may be "ideally suited to class certification" particularly where the central allegation is a common defect in a product that is purchased, ingested or used by all class members.[19]

When product liability claims *do* fail certification, it is usually because they founder for want of commonality or preferability; typically when the plaintiffs' expert evidence fails to disclose a "workable methodology" to prove causation of damage on a class-wide basis.[20]

However, two recent class actions in Canada failed at the certification stage—largely for different reasons. The valsartan and ranitidine class actions in B.C. and Ontario demonstrate the challenges with claims predicated entirely on the risk of future injury due to exposure to a harmful product or substance.

II. The Canadian Valsartan and Ranitidine Litigation

Like the FDA and other food and drug agencies, Health Canada has been investigating nitrosamine impurities in various medications for many years.[21] In the summer of 2018, several medications containing the active ingredient valsartan (an angiotensin II receptor blocker used to treat high blood pressure and other conditions) were recalled in Canada and elsewhere because a nitrosamine impurity, N-nitrosodimethylamine (NDMA) was found in the active pharmaceutical ingredient (API).[22] Similar nitrosamine impurities, including N-nitrosodiethylamine (NDEA), were subsequently found in both

35661 (Mar. 13, 2014); O'Brien v. Bard Canada Inc., [2015] ONSC 2470 (Can. Ont.); Chartrand v. General Motors Corporation, [2008] BCSC 1781 (Can. B.C.); Clark v. Energy Brands Inc., [2014] BCSC 1891 (Can. B.C.); *Palmer*, *supra* note 2; *Dussiaume* supra note 1; Price v. Lundbeck, [2024] ONSC 845 (Can. Ont.).

[19] Barwin v. IKO, [2012] ONSC 3969, para. 51 (Can. Ont.); Chace v. Crane Canada Inc., [1997] CanLII 4058, para. 16 (Can. B.C. C.A.); Walls et al. v. Bayer Inc., [2005] MBQB 3, para. 52 (Can. Man.).

[20] *See Charlton*, *supra* note 18, at paras. 61-113; Organigram Holdings Inc. v. Downton, [2020] NSCA 38, paras. 69-70 (Can. NS); *and* Vester v. Boston Scientific Ltd., [2015] ONSC 7950, paras. 130-131 (Can. Ont.).

[21] Health Canada, "Nitrosamine impurities in medications: Guidance," (last modified May 31, 2024) available at https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/nitrosamine-impurities/medications-guidance.html.

[22] Health Canada, "Impurities found in certain angiotensin II receptor blocker (ARB) products, also known as sartans," (last modified April 29, 2019) available at https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/angiotensin-receptor-blocker.html.

valsartan and other angiotensin II receptor blockers.[23]

Following the valsartan recalls, ranitidine products used to treat heartburn and similar symptoms were recalled in Canada and elsewhere after findings in late 2019 that some products may have contained NDMA in excess of the FDA's recommended daily intake levels.[24] Companies selling products in Canada voluntarily recalled lots of ranitidine or stopped selling ranitidine altogether.[25] Nitrosamine impurities including NDMA and NDEA, which have been found in angiotensin receptors and ranitidine, are classified as probable human carcinogens based primarily on animal studies.[26]

However, regulators, including both the FDA[27] and Health Canada,[28] have advised there is no immediate health risk associated with the use of medications containing low levels of NDMA or NDEA, which are ubiquitous and found in many common foods and beverages, drinking water, and the natural environment.

Spurred by the recalls, market withdrawals, citizen's petitions, and reporting in the scientific and lay press,[29] class counsel in various jurisdictions launched a wave of litigation involving medications with nitrosamine impurities. Canada was not spared. In *Dussiaume*,[30] the plaintiffs sought to certify an action on behalf of a class of Canadians who took ranitidine. In *Palmer*,[31] the plaintiffs sought to certify an action on behalf of a class of Canadians who took valsartan.

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[23] *Id.*

[24] Health Canada, "Status of ranitidine drugs in Canada," (posted July 23, 2020) available at https://recalls-rappels.canada.ca/en/alert-recall/status-ranitidine-drugs-canada.

[25] Health Canada, "Ranitidine products recalled because of a nitrosamine impurity," (last modified March 11, 2022) available at https://recalls-rappels.canada.ca/en/alert-recall/ranitidine-products-recalled-because-nitrosamine-impurity.

[26] Health Canada, "Nitrosamine impurities in medications: Overview," (last modified July 26, 2024) available at https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/nitrosamine-impurities.html.

[27] United States Food and Drug Administration, "Information about Nitrosamine Impurities in Medications," (last updated September 4, 2024) available at https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications.

[28] Health Canada, "Nitrosamine impurities in medications: Overview", *supra* note 26.

[29] *See* Editorial, "The Zantac Scare and Junk Science," WALL ST. J., (Dec. 8, 2022).

[30] *Dussiaume*, *supra* note 1.

[31] *Palmer ONCA*, *supra* note 2.

In *Dussiaume*, the plaintiffs purported to amend their claim to include allegations that certain class members had suffered certain types of cancers from "long-term" exposure to ranitidine, but the claim in reality pleaded causation of increased *risk* as opposed to causation of actual disease.[32] In *Palmer*, the plaintiffs expressly disclaimed any allegation that class members developed cancers from valsartan due to NDMA or NDEA exposure.[33]

In both cases, the plaintiffs claimed all class members suffered genotoxic injury, pure economic losses (such as costs of medical expenses and monitoring, refunds, costs for disposing the drugs), and psychological injury based on the present anxiety associated with the alleged increased risk of contracting cancer.[34]

At first instance, class certification was denied in *Palmer* and the court dismissed the action.[35] *Dussiaume* was dismissed summarily on a defense application for judgment, which the court agreed to hear and decide at the same time as the certification hearing.[36] The plaintiffs did not appeal *Dussiaume*. The Court of Appeal for Ontario upheld the dismissal of *Palmer* on March 27, 2024.[37]

A. Genotoxic Harm Rejected

The courts in *Palmer* and *Dussiaume* dismissed the claims for "genotoxic harm", an issue that had not been previously litigated in Canada. Borrowing from United States cases deciding that genotoxic harm may be sufficient for Article III standing,[38] the plaintiffs in each case alleged that nitrosamine impurities in the medication caused changes at the cellular or molecular level that increased the risk of contracting cancer.

The Canadian courts dismissed these claims primarily on the basis that the allegations pleaded did not disclose a viable cause of action in negligence. Compensable damage —an essential element of negligence—was not satisfied by a bare pleading of increased risk arising from genetic or cellular change. Both *Dussiaume*[39] and

[32] *Dussiaume*, *supra* note 1, at para. 45.
[33] *Palmer ONCA*, *supra* note 2, at paras. 3-4.
[34] *Dussiaume*, *supra* note 1, at paras. 38-41; *Palmer ONCA*, *supra* note 2, at paras. 42-80.
[35] *Palmer ONSC*, *supra* note 2.
[36] *Dussiaume*, *supra* note 1, at paras. 13-26.
[37] *Palmer ONCA*, *supra* note 2.
[38] *In re* Valsartan, Losartan and Irbesartan Products Liability Litigation, 2021 WL 100204 (D. N.J. Jan 12, 2021); Reilly v. Ceridian Corp., 664 F.3d 38, 45 (3d Cir. 2011); Carlough v. Amchem Prods., Inc., 834 F. Supp. 1437, 1447, 1454 (E.D. Pa. 1993).
[39] *Dussiaume*, *supra* note 1, at para. 61.

Palmer[40] held that such "genotoxic harm" is not, without more, a cognizable injury. Therefore, the necessary damage element of the damage element necessary for a claim in negligence was lacking.[41]

The decisions make clear that an allegation of genotoxicity itself is insufficient for a viable claim in negligence in Canada, bringing Canadian law in line with states which have rejected claims for purely "subclinical" injuries.[42]

B. Emotional Harm for Cancer Worry Rejected

Palmer and *Dussiaume* also held that the psychological injury claims based on the present anxiety of contracting cancer were doomed to fail, though each for different reasons.

The motion judge in *Palmer* and the court in *Dussiaume* suggested that psychological distress based on a fear of future harm (i.e. contracting cancer) is not compensable in tort in the absence of a physical injury (i.e. a cancer diagnosis).[43] This reasoning is consistent with the law in some United States states that physical injury or "impact" is required for claims for the fear of future disease.[44]

By contrast, the Court of Appeal for Ontario in *Palmer* held that if a mental injury arising from the fear of contracting a future disease is sufficiently significant it *may* be compensable, even in the absence of actual physical injury in the form of a cancer diagnosis. The Court of Appeal's decision is consistent with the law in those states that have rejected a requirement for physical impact or injury.[45]

The Court of Appeal in *Palmer* held that the plaintiffs had failed to allege facts that met the Canadian legal thresholds for recovery.[46] To be compensable in Canada, a

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[40] *Palmer ONCA*, *supra* note 2, at paras. 42-52.

[41] *Dussiaume*, *supra* note 1, at para. 46; *Palmer ONCA*, *supra* note 2, at paras. 48-49.

[42] *See e.g.* Amendola v. Kansas City Southern Ry. Co., 699 F. Supp. 1401 (W.D. Mo. 1988); Boyd v. Orkin Exterminating Co., Inc., 191 Ga. App. 38 (Ga. Ct. App. 1989), cert. denied, 191 Ga. App. 38 (Ga. Ct. App. 1989).

[43] *Dussiaume*, *supra* note 1 at paras. 71-75; *Palmer ONSC*, *supra* note 2, at para. 11.

[44] *See e.g.* McAdams v. Eli Lilly & Co., 638 F. Supp. 1173, 1178 (N.D. Ill. 1986); Carroll v. Sisters of Saint Francis Health Services, 868 S.W.2d 585, 593, 593-594 (Tenn. 1993); Landry v. Florida Power & Light Corp., 799 F. Supp. 94, 96 (S.D. Fla. 1992), aff'd., 998 F.2d 1021 (11th Cir. Fla. 1993); Eagle–Picher Indus., Inc. v. Cox, 481 So.2d 517, 520 (Fla. 3d Dist. Ct. App. 1985).

[45] *See e.g.* Lavelle v. Owens-Corning Fiberglas Corp., 507 N.E.2d 476 (Ohio Com. Pleas 1987); Faya v. Almaraz, 329 Md. 435, 456 (Md.1996).

[46] *Palmer ONCA*, *supra* note 2, at paras. 58-61.

mental injury must be (1) sufficiently serious and prolonged and rise above the ordinary annoyances, anxieties and fears that come with living in a civil society; and (2) the foreseeable consequence of the defendant's negligence, when viewed from the standard of a person of "ordinary fortitude".[47] The Court of Appeal in *Palmer* concluded that the complaint met neither threshold on the allegations pleaded—a conclusion largely driven by the extremely modest incremental risk estimates from NDMA exposure in valsartan published by Health Canada.[48]

While *Palmer* and *Dussiaume* dismissed the psychological claims for different reasons, the cases suggest that claims for the emotional distress of contracting a future disease like cancer will be difficult to sustain in Canada going forward, particularly if the evidence of a causal connection between the product and disease is weak or remote.

C. Medical Monitoring and Refund Claims Rejected

The plaintiffs in *Palmer* and *Dussiaume* sought to recover for pure economic losses in the form of expenses for medical monitoring, refunds and the disposal cost of the product. Each of these claims failed.

Under Canadian law, damages for "pure economic loss" in the absence of injury to person or property are exceptional. The "liability rule" for pure economic loss claims compensates a plaintiff for the cost of *averting* an imminent risk or real and substantial danger associated with a dangerous product or building structure.[49] Pure economic loss in negligence does not extend to refunds of the purchase price of an allegedly defective product.[50] In the Canadian valsartan and ranitidine litigations, the alleged defect was nitrosamine contamination, and the medications could easily be discarded, averting any danger.[51]

Palmer and *Dussiaume* also strongly suggest that under Canadian law, medical monitoring

[47] *Id.* citing Mustapha v. Culligan of Canada Ltd., [2008] 2 S.C.R. 114; Saadati v. Moorhead, [2017] 1 S.C.R. 543.

[48] *Palmer ONCA*, *supra* note 2, at paras. 68-69.

[49] Winnipeg Condominium Corp. No. 36 v. Bird Construction Co., [1995] 1 S.C.R. 85, paras. 30, 36 (Can.).

[50] *Palmer ONCA*, *supra* note 2, at paras. 77-79. In some circumstances, refunds may be available under provincial legislation, but the statutory consumer protection claims were dismissed in *Dussiaume* and *Palmer*. *See Palmer ONCA*, *supra* note 2, at paras. 83-93.

[51] *Dussiaume*, *supra* note 1; *Palmer ONCA*, *supra* note 2, at para. 78.

claims require proof of actual physical injury. The Court of Appeal for Ontario expressly stated in *Palmer* that "[m]edical monitoring presumes a physical injury" and "[w]here 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 in negligence 'in the air.'"[52]

The decisions bring Canadian law in line with those United States cases that have barred recovery for medical monitoring arising from alleged harm to a toxin absent actual physical injury.[53]

III. Approach to Scientific Evidence

While most Canadian courts have been reluctant to delve into scientific evidence at class certification, the *Palmer* and *Dussiaume* decisions make clear that there is a role for courts to scrutinize and dismiss claims based on weak science at, or even before, certification.

While making clear that he was not resolving a "battle of the experts", the motion judge in *Palmer* found that the plaintiffs failed to meet the low "some basis in fact" standard at certification for concluding that there was a causal relationship between valsartan and cancer.[54]

In *Dussiaume*, the court agreed to hear an application to summarily dismiss the plaintiffs' claims at the same time as certification, which, although available, is not the "norm" in Canada. In addition to the legal flaws in the plaintiffs' claim discussed above, the *Dussiaume* court found that the plaintiff had failed to raise a triable issue for actual injury given the expert evidence that NDMA from ranitidine was not reliably associated with increased cancer risk and the lack of evidence that NDMA from ranitidine causes cancer in humans.[55]

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[52] *Palmer ONCA*, *supra* note 2, at para. 79, citing Dow Chemical Company v. Ring, Sr., [2010] NLCA 20 (Can. NL.), at para. 57.

[53] *See e.g.* Wood v. Wyeth-Ayerst Laboratories, Div. of American Home Products, 82 S.W.3d 849, 859 (Ky. 2002); Greenberg v. McCabe, 453 F. Supp. 765, 773 (E.D. Pa. 1978), aff'd, 594 F.2d 854 (3d Cir. 1979); Villari v. Terminix Intern., Inc., 663 F. Supp. 727, 735 (E.D. Pa. 1988).

[54] *Palmer ONSC*, *supra* note 2, at para. 88. Interestingly, the motion judge held that there was a basis in fact for the proposition that exposure to NDMA and NDEA in contaminated valsartan very modestly increases the risk of being diagnosed with cancer; *id.*, at para. 103.

[55] *Dussiaume*, *supra* note 1, at para. 94.

The decisions in *Palmer* and *Dussiaume* are encouraging for defendants and suggest that despite the low certification thresholds, there may be meaningful opportunities to dismiss Canadian claims based on weak science early.