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Product Liability Update: Q1 2024

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Key Product Liability Cases: Q1 2024 Update

The Product Liability and Mass Torts Group at McCarthy Tétrault LLP is pleased to bring you our analysis of recent decisions for businesses manufacturing or selling products in Canada:

1. Ontario Court of Appeal Clarifies Standards for Compensable Psychological Injury in Product Liability Claims: ***Palmer v. Teva***

2. Ontario's Divisional Court Upholds Denial of Certification in a Pharmaceutical Class Action: ***Price v. Lundbeck***

3. General Motors Settles Canadian Ignition Switch Economic Loss Claims for $12M+: ***Oberski v. General Motors LLC***

4. Court of Appeal for Ontario Clarifies Application of Ontario's Amended *Class Proceedings Act*: ***Martin v. Wright Medical Technology Canada Ltd.***

Ontario Court of Appeal clarifies standards for compensable psychological injury in product liability claims: ***Palmer v. Teva***

On March 27, 2024, the Court of Appeal for Ontario released its much-awaited decision in *Palmer v. Teva*.[1] The decision sends a clear signal that claims based on weak science and remote or tenuous risks of future injury are unlikely to be certified. It is consistent with the clear trend in the Ontario jurisprudence refusing to certify class actions in the absence of compensable injury to class members.[2]

Background

Palmer v. Teva is one of a number of proposed class actions in Canada alleging psychological damage from the alleged increased risk of cancer resulting from exposure to nitrosamine impurities, which have been found in various prescription and over-the-counter medications.[3] *Palmer* concerned allegations that the defendants' valsartan blood pressure medications contained N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA). NDMA and NDEA are ubiquitous and can be found in common foods and beverages, drinking water, and the air. NDMA and NDEA are not harmful at low levels and the FDA sets recommended daily intake limits for NDMA, NDEA and other nitrosamines.

Perell J. denied certification in *Palmer* in August 2022.[4] In 2023, the B.C. Supreme Court summarily dismissed a similar action involving allegations of unacceptable levels of NDMA in ranitidine heartburn medications.[5]

In *Palmer*, the defendant manufacturers voluntarily recalled certain lots of valsartan products after discovering that the active pharmaceutical ingredient might contain NDMA and NDEA following manufacturing process changes. In the summer of 2018, Health Canada issued consumer bulletins relating to the defendants' valsartan recalls, but advised patients that they should continue taking their medications unless advised to the contrary by a physician or pharmacist. One of Health Canada's bulletins advised that based on the levels of NDMA found in valsartan, the potential increased risk of cancer over a lifetime was between 1:11,600 and 1:93,400 (i.e. one additional cancer case for every 11,600 or 93,000 people taking the product). The bulletin further put these figures into context, noting that "nearly 1 in 2 Canadians is expected to develop cancer during their lifetime."

The *Palmer* plaintiffs did *not* seek compensation for consumers who had been or may be diagnosed with any cancer as a result of consuming valsartan. Rather, they claimed for damages for the potential increased *risk* of being diagnosed with cancer in the future, as well as costs for medical services and monitoring, refunds for medications consumed, costs for medications thrown away, and psychological and punitive damages.

In dismissing the certification motion and the action, Perell J. found that there was no basis in fact for concluding there is a causal relationship between valsartan and cancer, but some basis in fact for the proposition that exposure

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[1] *Palmer v. Teva*, 2024 ONCA 220.

[2] See e.g. *Hoy v. Expedia Group, Inc.*, 2024 ONSC 1462 (Div. Ct.), at para. 85.

[3] See Health Canada, "Nitrosamine impurities in medications: Overview", online: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/nitrosamine-impurities.html.

[4] *Palmer v. Teva*, 2022 ONSC 4690.

[5] *Dussiaume v. Sandoz Canada Inc.*, 2023 BCSC 795.

to NDMA and NDEA in contaminated valsartan very modestly increases the risk of being diagnosed with cancer. He found that a small proportion of class members will have sustained psychological harm for a relatively short period, but that it was plain and obvious that neither the risk of future physical or psychological harm nor the present anxiety occasioned by that risk is compensable in law. Perell J. also found that the plaintiffs failed to satisfy the commonality and preferability criteria.

The plaintiffs appealed to the Court of Appeal for Ontario.

Outcome and Key Takeaways

In a long-awaited decision written by B.W. Miller J.A. (Huscroft and Paciocco JJ.A., concurring), the Court of Appeal unanimously affirmed Perell J.'s decision. The Court of Appeal's decision clarifies at least nine important principles in claims involving exposure to potentially harmful products and substances:

1. **Actual damage (physical or psychological) is an essential element of a claim in negligence.** Therefore, mere allegations of damage that have never materialized, and may never materialize, are doomed to fail.

2. **Claims for genotoxic injury (i.e. cellular or molecular changes) without more are generally insufficient to establish actual damage in negligence**. As the Court stated, "[a] physical change with no perceptible effect upon one's health is not compensable in negligence."[6]

3. **Claims for present psychological harm based on the risk of future injury may be compensable, but only if both aspects of the test in *Mustapha*[7] and *Saadati*[8] are met**. The Court of Appeal clarified that the Supreme Court of Canada's decisions in *Mustapha* and *Saadati* have two aspects: (1) a basic threshold for injury; and (2) an ordinary fortitude standard. The plaintiffs' claim failed to meet the basic threshold because it pled no material facts establishing mental injury that rose above the ordinary annoyances, anxieties and fears experienced by people living in civil society. The plaintiffs' claim would have also foundered on the ordinary fortitude standard; the Health Canada bulletins assuaged, rather than inflamed, consumers' concerns.

4. **The test for pure economic loss requires *imminent* risk of a real and substantial danger.** The basis for recovery for pure economic loss – that the plaintiff must take steps to prevent an imminent injury that it would otherwise suffer – "vanishes where the defect presents no imminent threat".[9] The plaintiffs' claims for medical expenses and medical monitoring failed in *Palmer* because it was plain and obvious that discarding the pills was sufficient to avert any danger and pure economic loss does not extend to other losses, such as product replacement value or refunds.

5. **Exposure to an allegedly contaminated product does not give rise to a claim in battery.** While battery can be committed intentionally or negligently, battery requires a direct, offensive, physical contact with the plaintiff, which is the immediate cause of the plaintiff's harm. And unlike negligence, battery cannot be based on a "failure to act", which is what the plaintiffs in *Palmer* alleged.

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[6] *Palmer v. Teva*, 2024 ONCA 220, at para. 52.

[7] *Mustapha v. Culligan of Canada Ltd.*, 2008 SCC 27, at para. 3.

[8] *Saadati v. Moorhead*, 2017 SCC 28.

[9] *Palmer v. Teva*, 2024 ONCA 220, citing *1688782 Ontario Inc. v. Maple Leaf Foods Inc.*, 2020 SCC 35, at para. 46.

6. **As with negligence, damage is an essential element of recovery for statutory claims for false, misleading, deceptive or unconscionable representations under the Ontario *Consumer Protection Act, 2002*.**[10] Section 18 of the Ontario *Consumer Protection Act, 2002* provides that the primary remedy for an unfair practice is rescission, but s. 18 also provides that "the consumer is entitled to any remedy that is available in law, including damages." Damages for an increase of a *risk* of harm or damages for mental injury that fail to meet the *Mustapha* and *Saadati* standards are not compensable "in law" under the statute.

7. **Failure to disclose a non-dangerous defect cannot constitute a "representation" under s. 52(1) of the *Competition Act***. Affirming prior decisions,[11] the Court of Appeal held that "[t]he object of s. 52(1) is to target deceptive marketing practices, not create liability for defective products."[12]

8. **Unjust enrichment claims against manufacturers for product defects are generally not viable.** The law of unjust enrichment does not permit recovery for incidental collateral benefits. In *Palmer*, any benefits received by the defendants from class members were indirect (because the purchase price for medications was paid to retailers, not the defendant manufacturers). Furthermore, the Court of Appeal held that plaintiffs do not suffer the element of "deprivation" required for a claim in unjust enrichment where they received the very product they bought. Class members paid for valsartan blood pressure medication and received it.

9. **Claims for psychological injury, even if compensable, may be uncertifiable if they are inherently idiosyncratic.** The Court of Appeal upheld the motion judge's finding that even if some claims for psychological harm based on fear of cancer were viable on the pleadings, at most, a minority of the class would have suffered compensable psychological injury based on the evidence. The "hard work" therefore remained for the individual issues trials and a common issues trial would have been of marginal utility.

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[10] *Consumer Protection Act, 2002*, S.O. 2002, c. 30, Sched. A.

[11] *Arora v. Whirlpool Canada LP*, 2013 ONCA 657, at paras. 50-51 citing *Williams v. Canon Canada Inc.*, 2011 ONSC 6571, at para. 227, aff'd on other grounds, *Williams v. Canon Canada Inc.*, 2012 ONSC 3692 (Div. Ct.).

[12] *Competition Act*, R.S.C., 1985, c. C-34.

Ontario's Divisional Court upholds denial of certification in a pharmaceutical class action: *Price v. Lundbeck*

In *Price v. Lundbeck*,[13] the Ontario Superior Court of Justice (Divisional Court) upheld Justice Glustein's decision to dismiss the Plaintiffs' certification motion, which we previously blogged about here. The plaintiffs alleged that the anti-depressant drug Celexa® was "teratogenic" – i.e. capable of causing birth defects to a fetus when consumed during pregnancy.

Key to the Divisional Court's decision was agreement with Glustein J. that plaintiffs cannot seize on superficial commonality by asking a question in a general way to satisfy the common issues criterion under s. 5(1)(c) of the *Class Proceedings Act*[14] if the question being asked is inherently individual. Further, the Divisional Court held that if the certification judge is satisfied that a class proceeding will not be fair, efficient, and manageable, then the judge need not perform a comparative analysis between a class action and other alternative proceedings to find that a class proceeding would not be the preferable procedure under s. 5(1)(d) of the *CPA*.

Background

A class action was commenced in December 2014 seeking to certify a class of Canadian women who used the anti-depressant drug Celexa® and subsequently miscarried or delivered children with congenital malformations. The defendants, H Lundbeck A/S and Lundbeck Canada Inc., were alleged to have manufactured, distributed, and marketed Celexa® in Canada without warning about the risk of teratogenicity.

The plaintiffs proposed to certify two common issues: 1) whether Celexa® was teratogenic, and 2) whether the defendant had failed to warn class members of Celexa®'s teratogenicity.

The evidence showed that, during any gestation, a fetus could suffer hundreds of different congenital malformations, each with its own unique cause and its own unique set of risks. Some problems were caused by genes, others by environmental exposures.

The plaintiffs did not try to prove that Celexa® caused any one particular congenital malformation, like a limb malformation. Instead, they tried to prove that Celexa® was a teratogen generally, such that it could allegedly cause any of the hundreds of alleged malformations. This decision to focus on generalized risk was described by the motion judge, Glustein J., as a "strategic choice." Among other things, it expanded the scope of the class because it enabled anyone who suffered any congenital problem after using Celexa® to be a class member.

Certification was denied (for the second time)[15] in December, 2022. Key to the certification judge's reasoning was that "[t]he plaintiffs led no evidence of a methodology to establish, on a class-wide basis, that Celexa® can cause any particular congenital malformation" [emphasis added]. He held that, even if the plaintiffs could show that Celexa® could cause congenital problems generally, class members would be claiming for harms caused by

[13] 2024 ONSC 845 (Div. Ct.).

[14] *Class Proceedings Act, 1992*, S.O. 1992, c. 6.

[15] Certification was denied for the first time by the Honourable Justice Perell in *Price v. H. Lundbeck A/S*, 2018 ONSC 4333 and was sent back for recertification by the Divisional Court in *Price v. H. Lundbeck A/S*, 2020 ONSC 913.

particular congenital problems, and therefore the proof of general risk would not bring any class member closer to showing that Celexa® had caused *their particular* congenital problem. Even if resolved in their favour, the proposed class action would not advance any of their individual claims.

The plaintiffs appealed the denial of certification to Ontario's intermediate court, the Divisional Court of the Ontario Superior Court of Justice.

Outcome and Key Takeaways

- The appeal was dismissed. The Court agreed with the certification judge that, to certify the question of whether a pharmaceutical defendant breached its duty to warn, the plaintiffs would need to show that the defendant failed to warn of a particular risk caused by its drug. A failure to warn of a risk of harm generally would not be sufficient.

- The Court also agreed that the proposed class action would not meaningfully advance the class members' claims. The question of whether Celexa® had the potential to cause generalized harm was a trivial or non-existent part of each class member's claim, since, again, their individual claims would be for particular harms. A class proceeding focused on answering the generalized question was not a preferable procedure for advancing the class members' claims.

General Motors Settles Canadian Ignition Switch Economic Loss Claims for $12M+: *Oberski v. General Motors LLC*

In *Oberski v. General Motors LLC*,[16] the Ontario Superior Court of Justice approved a C$12 million settlement of claims against General Motors for economic loss in respect of defective ignition switches, ignition keys, and power steering units in certain GM vehicles. The settlement was made on behalf of a national class (although approval of the Québec part of the class would need to be sought in Québec). The settlement also includes a process for resolving personal injury, wrongful death, and *Family Law Act* claims, in which a neutral third-party will examine each claimant's case and allocate a confidential settlement amount in exchange for a release. Any claims not resolved through this process can be pursued through individual litigation.

The *Oberski* settlement also includes a settlement of two related Québec actions, which will be authorized (certified) for the purpose of settlement by the Québec court. Similar economic loss claims in the United States were resolved in United States multidistrict litigation in 2020.

[16] 2024 ONSC 345.

Court of Appeal for Ontario Clarifies Application of Ontario's Amended *Class Proceedings Act*: ***Martin v. Wright Medical Technology Canada Ltd.***

Ontario class actions are subject to one of two versions of the *Class Proceedings Act, 1992*: an older version if they began before October 1, 2020, and a newer, amended version if they began after October 1, 2020. In general, counsel acting on behalf of plaintiffs would prefer that the older Act apply, because it contains an easier test for certification. All cases subject to the "old" Act were required to progress to a certain point by October 1, 2021, or be dismissed.

In *Martin v. Wright Medical Technology Canada Ltd.*,[17] the Court of Appeal for Ontario held that if a class action subject to the old Act is discontinued, it cannot be "revived" under the old Act by tacking its claims onto a different class action subject to the old Act. Assuming the discontinued class action can be restarted, it must be restarted under the new Act. Older class actions cannot be used as vehicles for bringing new claims under the old Act.[18]

Background

Two class actions were commenced in 2014, asking whether the defendant, Wright Medical Technology Canada Ltd., and two affiliates, negligently manufactured a prosthetic hip implant. The first action, started by Sandra Martin (and another), asked whether the hip implant had been negligently manufactured for one kind of surgery ("resurfacing") (the "Martin Action"). The second, started by Gayle Rowland, asked whether the hip implant had been negligently manufactured for another kind of surgery ("arthroplasty") (the "Rowland Action"). Different class counsel represented the plaintiffs in each action.

The Rowland Action became subject to mandatory dismissal after October 1, 2021 because it had not sufficiently progressed. The Martin Action had sufficiently progressed by October 1, 2021, so it was due to continue under the old Act.

All parties agreed that the Rowland action could be discontinued and restarted under the new Act. But class counsel for both Rowland and Martin wanted to amend the Martin Action to include the Rowland Action's claims, so that the Rowland claims could remain subject to the more plaintiff-friendly provisions of the old Act.

The motion judge did not permit this: he agreed that the Martin Action could be amended to include the Rowland claims, but held that the combined action would be subject to the *amended* Act, not the old Act. Both the defendants and class counsel for Martin appealed.

[17] 2024 ONCA 1.

[18] 2024 ONCA 1, at para. 31.

Outcome and Key Takeaways

Appeal allowed: the Rowland Action could be discontinued and restarted under the new Act, but the Martin Action would continue under the old Act. The two actions would remain separate, and could be tried separately or together.

- The amended Act required the Martin Action to proceed under the old Act. It clearly provided that the old Act would apply to actions started before October 1, 2020, which the Martin Action did. In the Court's view, the language of the amended Act "could not be clearer" – it drew a bright line between actions begun before and after October 1, 2020. The motion judge was not permitted to disregard the clear language of the Act, and force an action begun before October 1, 2020 to proceed under the amended Act.

- The Court considered but dismissed the argument that it would be "unmanageable and unworkable" for two different certification tests to apply to the Martin and Rowland actions.[19]

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[19] *Martin v. Wright Medical Technology Canada Ltd.*, 2024 ONCA 1, at para. 34.

For more information, please contact one of the authors noted below or another member of our Product Liability and Mass Torts Group.

BYRON SHAW

Byron is a Toronto litigation partner with extensive expertise in product liability, including a particular focus on litigation relating to pharmaceutical products and devices and consumer products and services. He has acted on some of the highest profile and complex product liability matters—often following recalls, market withdrawals and other regulatory action in Canada, the U.S. and other jurisdictions. Byron regularly acts as litigation counsel in product liability class actions and mass tort inventory litigation in all courts across the country.

bdshaw@mccarthy.ca
416-601-8256

DOROTHY CHARACH

Dorothy is a partner in our Litigation & Dispute Resolution Group in Toronto and Co-leader of our Health Industry Group. She maintains a broad practice with an emphasis on product liability, class actions, commercial litigation and dispute resolution, professional negligence, and defamation. Dorothy has appeared before numerous courts and tribunals, including the Ontario Court of Appeal, the Divisional Court of Ontario, the Ontario Superior Court, the Ontario Court of Justice, and the Health Professions Appeal and Review Board. She has experience serving as lead counsel at trial and on appeal.

dcharach@mccarthy.ca
416-601-7710

GREG RINGKAMP

Greg is an associate in our Litigation and Dispute Resolution Group, focusing primarily on product liability. Graduating from the University of Toronto's Faculty of Law, he received distinction standing and the Samuel and Clara Shime Award for Achievement in Law and Medicine. Prior to law school, Greg was a research ethics officer at the Montreal Neurological Institute, where he worked on experimental drug trials.

gringkamp@mccarthy.ca
416-601-7817

About McCarthy Tétrault's Product Liability and Mass Torts Group

Product liability and mass tort claims are among the most serious challenges an organization can face. When the survival of a brand or a business hangs in the balance, the world's leading companies turn to McCarthy Tétrault. Our deep bench strength and expertise across Canada allows us to help our clients navigate their most complex product liability and mass tort challenges from start to finish. We act for companies in a wide range of matters and industries, including medical products and devices, consumer products and services, transportation and automotive products, toxic chemical and environmental matters, and catastrophic events. Our firm's integrated, industry-focused approach allows us to anticipate issues and help prevent and contain product liability and mass tort lawsuits before they begin.

mccarthy tétrault

VANCOUVER

Suite 2400, 745 Thurlow Street
Vancouver BC V6E 0C5
Tel: 604-643-7100
Fax: 604-643-7900

QUÉBEC CITY

500, Grande Allée Est, 9e étage
Québec QC G1R 2J7
Tel: 418-521-3000
Fax: 418-521-3099

CALGARY

Suite 4000, 421 7th Avenue SW
Calgary AB T2P 4K9
Tel: 403-260-3500
Fax: 403-260-3501

NEW YORK

55 West 46th Street, Suite 2804
New York NY 10036
UNITED STATES
Tel: 646-940-8970
Fax: 646-940-8972

TORONTO

Suite 5300, TD Bank Tower
Box 48, 66 Wellington Street West
Toronto ON M5K 1E6
Tel: 416-362-1812
Fax: 416-868-0673

LONDON

1 Angel Court, 18th Floor
London EC2R 7HJ
UNITED KINGDOM
Tel: +44 (0)20 7786 5700
Fax: +44 (0)20 7786 5702

MONTRÉAL

Suite MZ400
1000 De La Gauchetière Street West
Montréal QC H3B 0A2
Tel: 514-397-4100
Fax: 514-875-6246